Name: National Institute for Food and Drug Control

Address: No.31, Huatuo Road, Daxing District, Beijing, China

Registration No. CNAS L0001

Accreditation Criteria: ISO/IEC 17025:2017 and relevant requirements of CNAS

Effective Date: 2026-07-28 Expiry Date: 2030-06-05

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SCHEDULE 3 ACCREDITED TESTING SCOPE

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
Drug						
1	Drug	1	Solubility	ChP 2025 Vol Ⅰ / Ⅱ / Ⅳ general notices		2026-07-28
		2	Weight variation	ChP 2025 Vol Ⅳ general rule (0100)		2026-07-28
		3	Foam volume	ChP 2025Vol Ⅳ general rule (0101)		2026-07-28
		4	Disintegration and uniformity of dispersion	ChP 2025 Vol Ⅳ general rule (0101)		2026-07-28
		5	Total number of deliveries per container;Total number of doses per container;Total number of discharges per	ChP 2025 Vol Ⅳ general rule (0111)		2026-07-28
				ChP 2025 Vol Ⅳ general rule (0112)		2026-07-28
				ChP 2025 Vol Ⅳ general rule (0113)		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			container			
		6	Leakage rate	ChP 2005 Vol Ⅱ Appendix Ⅰ L		2026-07-28
		7	Content of active ingredient in an actuation;Content of active ingredient in a dose;Content of active ingredient in a Unit Spray	ChP 2025 Vol Ⅳ general rule (0111)		2026-07-28
				ChP 2025 Vol Ⅳ general rule ((0112)		2026-07-28
				ChP 2025 Vol Ⅳ general rule (0113)		2026-07-28
		8	Inhaled percentage	ChP 2010Vol Ⅱ Appendix Ⅰ L		2026-07-28
		9	Delivery rate	ChP 2025 Vol Ⅳ general rule (0113)		2026-07-28
		10	Total amount of spray	ChP 2025 Vol Ⅳ general rule (0113)		2026-07-28
		11	Delivery amount in a dose	ChP 2025 Vol Ⅳ general rule (0112)		2026-07-28
		12	Optical Rotation	ChP 2025 Vol Ⅳ general rule (0621)		2026-07-28
		13	Refractive Index	ChP 2025 Vol Ⅳ general rule (0622)		2026-07-28
		14	Acid Value	ChP 2025 Vol Ⅳ general rule (0713)		2026-07-28
		15	Saponification Value	ChP 2025Vol Ⅳ general rule (0713)		2026-07-28
		16	Hydroxyl Value	ChP 2025 Vol Ⅳ general rule (0713)		2026-07-28
		17	Iodine Value	ChP 2025 Vol Ⅳ general rule (0713)		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Peroxide Value	ChP 2025Vol Ⅳgeneral rule (0713)		2026-07-28
		19	Vitamin A	ChP 2025 Vol Ⅳgeneral rule (0721)		2026-07-28
		20	Vitamin D	ChP 2025 Vol Ⅳgeneral rule (0722)		2026-07-28
		21	Readily Carbonizable Substances	ChP 2025 Vol Ⅳgeneral rule (0842)		2026-07-28
		22	THERMAL ANALYSIS	ChP 2025 Vol Ⅳgeneral rule （0661）		2026-07-28
		23	Total organic carbon	ChP 2025 Vol Ⅳgeneral rule (0682)		2026-07-28
		24	Conductance	ChP 2025 Vol Ⅳgeneral rule (0681)		2026-07-28
		25	Determination of Disintegration	ChP 2025 Vol Ⅳgeneral rule (0921)		2026-07-28
		26	Dissolution Test	ChP 2025 Vol Ⅳgeneral rule (0931)		2026-07-28
		27	Drug Release Test	ChP 2025 Vol Ⅳgeneral rule (0931)		2026-07-28
		28	Tablet Friability	ChP 2025 Vol Ⅳgeneral rule (0923)		2026-07-28
		29	Aerodynamic Assessment of Fine Particles	ChP 2025 Vol Ⅳgeneral rule (0951)		2026-07-28
		30	Identification/Ispect	ChP 2025 Vol Ⅳgeneral rule (identification) (0301)		2026-07-28
				ChP2025 Vol Ⅳ General Chapter (Molecular-exclusion Chromatography) (0514)		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2025 Vol Ⅳgeneral rule (High Performance Liquid Chromatography) (0512)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (ion chromatography) (0513)		2026-07-28
				ChP2025 Vol Ⅰ / Vol II/Vol Ⅳ（Volumetric Analysis）		2026-07-28
				ChP 2025Vol Ⅳgeneral rule (Infrared Spectrophotometry) (0402)		2026-07-28
				USP-NF <584>（2023）		2026-07-28
				EP 11 <2.2.24>		2026-07-28
				Ph.Int. 2022 <1.7>		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Gas Chromatography) (0521)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Raman spectroscopy (0421)		2026-07-28
				USP-NF <1120>（2023）		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Thin-layer Chromatography) (0502)		2026-07-28
				EP11 <2.2.27>		2026-07-28
				USP-NF <201>（2023）		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule(Electrophoresis) (0541)		2026-07-28
				EP 11 (Capillary Electrophoresis) <2.2.47>		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Spectrophotometry and Light-		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Scattering) (0401)		
				ChP 2025 Vol Ⅳgeneral ruleICP-OES （0411）		2026-07-28
				USP-NF <611>（2023）		2026-07-28
				Chp 2025 Vol Ⅳgeneral rule(paper chromatography) 0501		2026-07-28
				USP-NF <621>（2023）		2026-07-28
				EP11 <2.2.26>		2026-07-28
				Ph.Int.2022 <1.14.2>		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule（MS） （0431）		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule（XRD） （0451）	Only method 2	2026-07-28
				ChP 2025 Vol Ⅳgeneral rule （0441）	Except for ssNMR	2026-07-28
		31	Related substances	ChP 2025 Vol Ⅳgeneral rule (High Performance Liquid Chromatography) (0512)		2026-07-28
				ChP2025 Vol Ⅳ General Chapter (Molecular-exclusion Chromatography) (0514)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (ion chromatography) (0513)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Determination of Optical Rotation) (0621)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Potentiometr-ic Titration and Dead-stop Titration) (0701)		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2025 Vol Ⅳ general rule (Non-aqueous Titration) (0702)		2026-07-28
				ChP2025 Vol Ⅰ / Vol II/Vol Ⅳ（Volumetric Analysis）		2026-07-28
				ChP2025 Vol Ⅰ / Vol II/Vol Ⅳ（Gravimetric Analysis）		2026-07-28
				ChP 2025 Vol Ⅳ general rule (Gas Chromatography) (0521)		2026-07-28
				ChP 2025 Vol Ⅳ general rule （Capillary Electrophoresis）（0542）		2026-07-28
				EP11 （Capillary Electrophoresis） <2.2.47>		2026-07-28
				ChP 2025 Vol Ⅳ general rule（ICP-OES） （0411）		2026-07-28
				USP-NF <611>（2023）		2026-07-28
				ChP 2025Vol Ⅳ general rule MS (0431)		2026-07-28
				ChP 2025 Vol Ⅳ general rule XRD (0451)	Only method 2	2026-07-28
				Chp 2025 Vol Ⅳ general rule(paper chromatography) 0501		2026-07-28
				USP-NF <621>（2023）		2026-07-28
				EP11 <2.2.26>		2026-07-28
				Ph.Int.2022 <1.14.2>		2026-07-28
		32	radiochemical purity	Chp 2025 Vol Ⅳ general rule(The test of Radiopharmaceutical Preparations) (1401)		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				EP12 0125 radiopharmaceutical preparations-page 943		2026-07-28
				USP-NF <1821>（2026）		2026-07-28
		33	radioactivity (radioactive concentration)	Chp 2025 Vol Ⅳgeneral rule(The test of Radiopharmaceutical Preparations) 1401		2026-07-28
				ChP2025 Vol II page 1971-1972		2026-07-28
				USP-NF <821>（2026）		2026-07-28
				EP12 <2.2.66>		2026-07-28
				Ph.Int.2024 <1.1>		2026-07-28
		34	radionuclide identification	Chp 2025 Vol Ⅳgeneral rule(The test of Radiopharmaceutical Preparations) 1401		2026-07-28
				USP-NF <1821>（2026）		2026-07-28
				EP12 <2.2.66>		2026-07-28
				Ph.Int.2024 <1.2>		2026-07-28
		35	radionuclidic purity	Chp 2025 Vol Ⅳgeneral rule(The test of Radiopharmaceutical Preparations) 1401		2026-07-28
				USP-NF <1821>（2026）		2026-07-28
				EP12 <2.2.66>		2026-07-28
				Ph.Int.2024 <1.3>		2026-07-28

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		№	Item/ Parameter			
		36	biodistribution	Chp 2025 Vol IV General Chapter 1402		2026-07-28
		37	size	Chp 2025 Vol Ⅱ page 1980		2026-07-28
		38	Surface contamination and leakage test	Chp 2025 Vol Ⅱ page 1980		2026-07-28
		39	radioimmunoassay kit testing	National standards for radioimmunoassay kit and general rules of radioimmunoassay kit WS1-(R-01-92)-2004Z		2026-07-28
		40	Assay	ChP 2025 Vol Ⅳgeneral rule (High Performance Liquid Chromatography) (0512)		2026-07-28
				ChP2025 Vol Ⅳ General Chapter (Molecular-exclusion Chromatography) (0514)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (ion chromatography) (0513)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Determination of Optical Rotation) (0621)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Potentiometr-ic Titration and Dead-stop Titration) (0701)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Non-aqueous Titration) (0702)		2026-07-28
				ChP2025 Vol Ⅰ / Vol II/Vol Ⅳ（Volumetric Analysis）		2026-07-28
				ChP2025 Vol Ⅰ / Vol II/Vol Ⅳ（Gravimetric Analysis）		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Gas Chromatography) (0521)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule（Protein content） (0731)		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule（Determination of acetic acid in		2026-07-28

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		№	Item/ Parameter			
				synthetic peptides） (0872)		
				ChP 2025 Vol Ⅳgeneral rule（ Capillary Electrophoresis）（0542）		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Spectrophotometry and Light-Scattering) （0401）		2026-07-28
				ChP 2025 Vol Ⅳgeneral rule ICP-OES （0411）		2026-07-28
				USP-NF <611>（2023）		2026-07-28
				Chp 2025Vol Ⅳgeneral rule (Microbiological Assay of Antibiotics) (1201)		2026-07-28
				Chp 2025 Vol Ⅳgeneral rule(AAS) (0406)		2026-07-28
				Chp 2025Vol Ⅳgeneral rule(MS) (0431)		2026-07-28
				Chp 2025Vol Ⅳgeneral rule(XRD) (0451)	Only method 2	2026-07-28
				ChP 2025 Vol Ⅳgeneral rule (Nuclear Magnetic Resonance Spectroscopy) (0441)	Except for ssNMR	2026-07-28
		41	Chlorides	ChP 2025 Vol Ⅳgeneral rule (0801)		2026-07-28
				USP-NF <221>（2023）		2026-07-28
				EP 11 <2.4.4>		2026-07-28
				Ph. Int. 2022 <2.2.1>		2026-07-28
		42	Sulfates	ChP 2025 Vol Ⅳgeneral rule (0802)		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				USP-NF <221>（2023）		2026-07-28
				EP 11 <2.4.13>		2026-07-28
				Ph.Int. 2022 <2.2.2>		2026-07-28
		43	Sulfide	ChP 2025 Vol Ⅳgeneral rule (0803)		2026-07-28
		44	Cyanides	ChP 2025 Vol Ⅳgeneral rule (0806)		2026-07-28
		45	Iron	ChP 2025 Vol Ⅳgeneral rule (0807)		2026-07-28
				USP-NF <241>（2023）		2026-07-28
		46	Heavy Metals	ChP 2025 Vol Ⅳgeneral rule (0821)		2026-07-28
				EP 11 <2.4.8>	only A/C/D	2026-07-28
				Ph.Int. 2022 <2.4.8>	only Method A	2026-07-28
		47	Ammonium	ChP 2025 Vol Ⅳgeneral rule (0808)		2026-07-28
				EP 11 <2.4.1>	only Method A	2026-07-28
		48	Description	ChP 2025 Vol Ⅳ		2026-07-28
		49	Inorganic iron	ChP2025 Vol Ⅰ / Vol II/Vol Ⅳ		2026-07-28
		50	Arsenic	ChP 2025Vol Ⅳgeneral rule (0822)		2026-07-28
		51	Ratio of sedimental volume	ChP 2025 Vol Ⅳgeneral rule (0105),(0106),(0123),(0126)		2026-07-28

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		№	Item/ Parameter			
		52	Metal particles	ChP 2025 Vol Ⅳ general rule (0105)		2026-07-28
		53	Determination of Dispersibility	ChP 2025 Vol Ⅳ general rule (0100)		2026-07-28
				ChP 2025 Vol Ⅳ general rule (0104)		2026-07-28
				ChP 2025 Vol Ⅳ general rule (0188)		2026-07-28
		54	Uniformity of appearance	ChP 2025 Vol Ⅳ general rule (0115)		2026-07-28
		55	2-Ethyl hexanoic acid	ChP 2025 Vol Ⅳ general rule (0873)		2026-07-28
		56	Solvent Residue	ChP 2025 Vol Ⅳ general rule (0861)		2026-07-28
		57	Color of Solution	ChP 2025 Vol Ⅳ general rule (0901)		2026-07-28
		58	Clarity of Solution	ChP 2025 Vol Ⅳ general rule (0902)		2026-07-28
		59	Particulate Matter	ChP 2025 Vol Ⅳ general rule (0903)		2026-07-28
		60	Determination of Particle Size	ChP 2025 Vol Ⅳ general rule (0104)		2026-07-28
				ChP 2025 Vol Ⅳ general rule (0982)		2026-07-28
		61	Minimum Fill	ChP 2025 Vol Ⅳ general rule (0942)		2026-07-28
		62	Melting Point	ChP 2025 Vol Ⅳ general rule (0612)		2026-07-28
				EP11 <2.2.14>		2026-07-28
				USP-NF <741>（2023）		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		63	pH Value	ChP 2025 Vol Ⅳ general rule (0631)		2026-07-28
				EP11 <2.2.3>		2026-07-28
				USP-NF <971>（2023）		2026-07-28
		64	Loss on Drying	ChP 2025 Vol Ⅳ general rule (0831)		2026-07-28
				EP11 <2.2.32>		2026-07-28
				USP-NF <731>（2023）		2026-07-28
		65	WATER DETERMINATION	ChP 2025 Vol Ⅳ general rule(0832)		2026-07-28
				EP11 <2.5.32>		2026-07-28
				USP-NF <921>（2023）		2026-07-28
		66	Residue on Ignition	ChP 2025 Vol Ⅳ general rule (0841)		2026-07-28
				EP11 <2.4.16>		2026-07-28
				USP-NF <281>（2023）		2026-07-28
		67	Content Uniformity	ChP 2025 Vol Ⅳ general rule (0941)		2026-07-28
				EP11 <2.9.6>		2026-07-28
				USP-NF <905>（2023）		2026-07-28
		68	Adhensive property	ChP 2025 Vol Ⅳ general rule (0952)		2026-07-28

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		№	Item/ Parameter			
				ChP 2025 Vol Ⅳ general rule (0121)		2026-07-28
				ChP 2025 Vol Ⅳ general rule (0122)		2026-07-28
		69	TDS adhesion tests	USP-NF <3>（2023）		2026-07-28
		70	Ointment wreight	ChP 2025 Vol Ⅳ general rule (0122)		2026-07-28
		71	Heat resistance	ChP 2025 Vol Ⅳ general rule (0122)		2026-07-28
		72	Transmittance of solution	ChP 2025 Vol Ⅳ general rule (0401)		2026-07-28
		73	Absorbance	ChP 2025 Vol Ⅳ general rule (0401)		2026-07-28
		74	Determination of Molecular Weight and Molecular Weight Distribution	ChP 2025 Vol Ⅳ general rule (0514)		2026-07-28
				European Pharmacopoeia 11 Page 3650		2026-07-28
		75	Protein Content	ChP 2025 Vol Ⅳ general rule (0731)		2026-07-28
		76	Acetic acid in synthetic polypeptide	ChP 2025 Vol Ⅳ general rule (0872)		2026-07-28
		77	assay of lyophilizing thrombin powder	CHP 2025 Vol II page 1845		2026-07-28
		78	assay of trypsin	CHP 2025 Vol II page 1395		2026-07-28
		79	assay of trypsin in pancreatin	CHP 2025Vol II page 1397		2026-07-28

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		№	Item/ Parameter			
		80	assay of pepsin	CHP 2025Vol II page 901		2026-07-28
		81	assay of chymotrypsin	CHP 2025 Vol II page 1880		2026-07-28
		82	assay of urokinase	CHP 2025 Vol II page 653		2026-07-28
		83	assay of asparaginase (Escherichia), asparaginase (Ervinia)	CHP 2025 Vol II page 50,52		2026-07-28
		84	assay of defibrase	National Drug Specifications Vol 16 page 88		2026-07-28
		85	assay of lysozyme	Ministry of health drug specifications Vol II ,sixth book,page141		2026-07-28
		86	assay of pancreatic kininogenase	CHP 2025 Vol II page 1399		2026-07-28
		87	Bacterial Endotoxin test	ChP 2025 Vol Ⅳ general rule 1143		2026-07-28
				ChP 2025 Vol Ⅳ general rule (9251)		2026-07-28
				USP -NF <85>（2020）		2026-07-28
				EP 11.4 <2.6.14>（2023）		2026-07-28
				JP 18 <4.01>(2021)		2026-07-28
		88	osmotic pressure	ChP 2025 Vol Ⅳ general notices (0632)		2026-07-28
		89	Visible foreign matter	ChP 2025 Vol Ⅳ general notices (0904)	Except Method III	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		90	Nitrogen	ChP 2025 Vol Ⅳ general rule Method3 (0704)		2026-07-28
		91	Specific absorbance	ChP 2025 Vol Ⅳ general rule (Spectrophotometry and Light-Scattering)0401 (0401)		2026-07-28
		92	molar substitution	ChP 2025 Vol Ⅳ general rule (0521)		2026-07-28
				Ministry of health drug specifications Vol II ,sixth book, Appendix 7		2026-07-28
				National Drug Specifications YBH15182006，YBH02202010		2026-07-28
		93	Viscosity	ChP 2025 Vol Ⅳ general rule (0633)		2026-07-28
		94	Hemorrhagic toxicity	National Drug Specifications Vol 16 page 88		2026-07-28
				Import Drug Registrations JX20010046		2026-07-28
		95	Neurotoxicity	National Drug Specifications Vol 16 page 88		2026-07-28
		96	Thymus peptide biological activity	National Drug Specifications Vol 16 page 118		2026-07-28
		97	Transfer factor biological activity	National Drug Specifications Vol 16 page 104		2026-07-28
		98	Crystallinity	ChP 2025 Vol Ⅳ general rule (0981)	Only the second method	2026-07-28
		99	Test for depressor substances	Chp 2025 Volume IV Chp 2015 Volume IV (1145)		2026-07-28
		100	assay of amylopsin in pancreatin	ChP 2025 Vol Ⅱ page 1397		2026-07-28
		101	assay of pancrelipase in	ChP 2025 Vol Ⅱ page 1397		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			pancreatin			
		102	activity determination	National Drug Specifications Vol 16 page 82		2026-07-28
		103	determination of immunogenicity	National Drug Specifications (Trial Implementation)WS1-XG-053-2000-2005		2026-07-28
		104	activity determination of Cytochrome C	ChP 2025 Vol Ⅳgeneral rule (1206)		2026-07-28
		105	shape forming ability	ChP 2025 Vol Ⅳgeneral rule (0122)		2026-07-28
		106	content of alcohol	ChP 2025 Vol Ⅳgeneral rule (0711)	only GC Mthod Ⅰ（capillary column chromatography）	2026-07-28
		107	Test for Undue Toxicity	Chp 2025Volume IV Chp 2015 Volume IV (1141)		2026-07-28
		108	Test for Allergen	Chp 2025 Volume IV Chp 2015 Volume IV (1147)		2026-07-28
		109	Test for Pyrogen	Chp 2025 Volume IV Chp 2015 Volume IV (1142)		2026-07-28
				General principles of four parts of Chinese Pharmacopoeia 2025 Edition（9301） Monocyte activationtest，MAT		2026-07-28
				EP 11.4 <2.6.8>(2023)		2026-07-28
				USP -NF 38 <151>（2020）		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		110	Test for Haemolysis and Agglomeration	Chp2025 volume IV Chp2015 volume IV（1148）		2026-07-28
		111	Biological Assay of Protamine Sulfate	Chp2025 volume IV Chp2015 volume IV（1213）		2026-07-28
		112	Biological Assay of Luteinsing Hormone	Chp2025 volume IV Chp2015 volume IV（1217）		2026-07-28
		113	Biological Assay of Vasopressin	Chp2025 Volume Ⅳ General Rules 1205		2026-07-28
		114	Biological Assay of pressor substance	Chp2025 volume IV General Rules 1144		2026-07-28
		115	Toxicity Test of Sodium Stibogluconate	Chp 2025 Volume IV Chp 2015 Volume IV (1215)		2026-07-28
		116	biopotency of chorionic gonadotrophin	ChP 2025Vol Ⅳgeneral rule (1209)		2026-07-28
		117	biopotency of Insulin	ChP 2025 Vol Ⅳgeneral rule (1211)		2026-07-28
				USP-NF <121>（2020）		2026-07-28
		118	potency of sollicle-stimulating hormone	ChP 2025 Vol Ⅳgeneral rule (1216)		2026-07-28
		119	biopotency of growth hormone	ChP 2025 Vol Ⅳgeneral rule (1219)		2026-07-28
		120	Disintegration test	ChP2025 Vol Ⅳ，general rule 0108		2026-07-28
		121		ChP2025 Vol. Ⅳ General Notices 1208		2026-07-28
		122	General quality control method for crude drugs	ChP2025 Vol Ⅳ，general rule 0212		2026-07-28

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		№	Item/ Parameter			
		123	arsenic	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2026-07-28
				ChP2025 Vol Ⅳ，general rule 2321		2026-07-28
		124	Microscopical indentification	ChP2025 Vol Ⅳ，general rule 2001		2026-07-28
		125	cadmium	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2026-07-28
				ChP2025 Vol Ⅳ，general rule 2321		2026-07-28
		126	Foreign Matter	ChP2025 Vol Ⅳ，general rule 2301		2026-07-28
		127	mercury	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2026-07-28
				ChP2025 Vol Ⅳ，general rule 2321		2026-07-28
		128	lead	ChP2025 Vol Ⅳ，general rule 2321		2026-07-28
				Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2026-07-28
		129	cobalt	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2026-07-28
		130	nickel	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2026-07-28
		131	vanadium	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2026-07-28
		132	copper	ChP2025 Vol Ⅳ，general rule 2321		2026-07-28
		133	palladium	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		134	Ash	ChP2025 Vol Ⅳ，general rule 2302		2026-07-28
		135	rhodium	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2026-07-28
		136	Indium	Inductively coupled plasma mass spectrometry ChP2025 Vol IV general notices 0412		2026-07-28
		137	Material about Injietion	ChP2025 Vol Ⅳ，general rule 2400		2026-07-28
		138	Methanol	ChP2025 Vol Ⅳ，general rule 0871		2026-07-28
		139	Residue of Sulfur Dioxide	ChP2025 Vol Ⅳ，general rule 2331		2026-07-28
		140	aflatoxin B1	ChP2025 Vol Ⅳ，general rule 2351		2026-07-28
		141	aflatoxin B2	ChP2025 Vol Ⅳ，general rule 2351		2026-07-28
		142	aflatoxin G1	ChP2025Vol Ⅳ，general rule 2351		2026-07-28
		143	aflatoxin G2	ChP2025 Vol Ⅳ，general rule 2351		2026-07-28
		144	zearalenone	ChP2025 Vol Ⅳ，general rule 2351		2026-07-28
		145	Extractives	ChP2025 Vol Ⅳ，general rule 2201		2026-07-28
		146	Tanninoids	ChP2025 Vol Ⅳ，general rule 2202		2026-07-28
		147	Cineol	ChP2025 Vol Ⅳ，general rule 2203		2026-07-28
		148	Volatile Oil	ChP2025 Vol Ⅳ，general rule 2204		2026-07-28
		149	polymerase chain reaction	ChP2025 Vol IV 1001		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		150	morphological identification	ChP2025 Vol I, the ordinary case		2026-07-28
2	drug	1	Drug Hygroscopicity	Part IV,General Chapters of the 2025 Edition of ChP 0961		2026-07-28
				Part IV, General Guidelines of the 2025 Edition of ChP 9103	Only use Method 2	2026-07-28
3	Chinese materia medica	1	Nitrofen	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）, Mthod V	2026-07-28
		2	Fipronil（Fipronil、Fipronil Desulfinyl、Fipronil Sulfone、Fipronil-Sulfide）	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）, Mthod V	2026-07-28
		3	Chlordimeform	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）, Mthod V	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Phorate（Phorate、Phorate-Sulfone、Phorate - Sulfoxide）	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）, Mthod V	2026-07-28
		5	Fenamiphos（Fenamiphos、Fenamiphos Sulfoxide、Fenamiphos Sulfone）	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）, Mthod V	2026-07-28
		6	Terbufos（Terbufos、Terbufos Sulfone、Terbufos-Sulfoxide）	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）, Mthod V	2026-07-28
		7	Coumaphos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-	2026-07-28

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		№	Item/ Parameter			
					MS/MS）, Mthod V	
		8	Sulfotep	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）, Mthod V	2026-07-28
		9	Cadusafos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）, Mthod V	2026-07-28
		10	Chlorsulfuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）, Mthod V	2026-07-28
		11	Ethametsulfuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					（only LC-MS/MS）, Mthod V	
		12	Metsulfuron-Methyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）, Mthod V	2026-07-28
		13	Isofenphos-Methyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）, Mthod V	2026-07-28
		14	Demeton(O+S)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）, Mthod V	2026-07-28
		15	Carbofuran	ChP ChP2025 Vol IV general notices 2341	general	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			（Carbofuran、Carbofuran-3-Hydroxy）		notices 2341 Mthod IV（only LC-MS/MS）, Mthod V	
		16	Aldicarb（Aldicarb、Aldoxycarb、Aldicarb-Sulfoxide）	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）, Mthod V	2026-07-28
		17	Ethoprophos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）, Mthod V	2026-07-28
		18	Isazofos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）,	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Mthod V	
		19	Isocarbophos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）, Mthod V	2026-07-28
		20	Phosfolan	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）, Mthod V	2026-07-28
		21	Phosfolan-Methyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）, Mthod V	2026-07-28
		22	Phosphamidon	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					（only LC-MS/MS）, Mthod V	
		23	Aldrin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）, Mthod V	2026-07-28
		24	Dieldrin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）, Mthod V	2026-07-28
		25	Dicofol	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）, Mthod V	2026-07-28
		26	Endosulfan	ChP ChP2025 Vol IV general notices 2341	general	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			（Endosulfan Sulfate）		notices 2341 Mthod IV（only GC-MS/MS）, Mthod V	
		27	Fonofos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）, Mthod V	2026-07-28
		28	Parathion	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）, Mthod V	2026-07-28
		29	Parathion-Methyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）,	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Mthod V	
		30	Methamidophos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）, Mthod V	2026-07-28
		31	Monocrotophos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）, Mthod V	2026-07-28
		32	HCH（α-BHC、β-BHC、δ-BHC、γ-BHC）	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod I(1), Mthod IV（only GC-MS/MS）, Mthod V	2026-07-28
		33	DDT（p,p'-DDE，o,p'-DDT，p,p'-DDT，p,p'-DDD）	ChP ChP2025 Vol IV general notices 2341	general notices 2341	2026-07-28

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		№	Item/ Parameter			
					Mthod I(1), Mthod IV（only GC-MS/MS）, Mthod V	
		34	Chlordane（Cis-Chlordane，Trans-Chlordane，Oxy-Chlordane）	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod I(1), Mthod IV（only GC-MS/MS）	2026-07-28
		35	Heptachlor（Heptachlor，Heptachlor -exo-epoxide，Heptachlor-endo-epoxide ）	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod I(1), Mthod IV（only GC-MS/MS）	2026-07-28
		36	Hexachlorobenzene	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod I(1), Mthod IV（only GC-MS/MS）	2026-07-28

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		№	Item/ Parameter			
		37	quintozene	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod I, Mthod IV （only GC-MS/MS）	2026-07-28
		38	Acephate	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		39	Alachlor	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		40	azinphos-ethyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28

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		№	Item/ Parameter			
		41	azinphos-methyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		42	Bromophos-Ethyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		43	Bromophos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		44	Bromopropylate	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		45	Chlorfenvinfos	ChP ChP2025 Vol IV general notices 2341	general	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					notices 2341 Mthod IV （only LC-MS/MS）	
		46	Chlorpyrifos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		47	Chlorpyrifos-Methyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		48	Chlorthal-Dimethyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		49	Cyfluthrin	ChP ChP2025 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					2341 Mthod IV（only GC-MS/MS）	
		50	Cyhalothrin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		51	Cypermethrin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		52	Deltamethrin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		53	Diazinon	ChP ChP2025 Vol IV general notices 2341	general notices 2341	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method		Note	Effective Date
		№	Item/ Parameter				
						Mthod IV（only GC-MS/MS）	
		54	Dichlofluanid	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		55	Dichlorvos	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		56	Dimethoate	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		57	Omethoate	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method		Note	Effective Date
		№	Item/ Parameter				
						（only LC-MS/MS）	
		58	Endrin	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		59	Ethion	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		60	Etrimfos	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		61	Fenchlorphos （Fenchlorphos、Fenchlorphos-Oxon）	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV （only	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					GC-MS/MS）	
		62	Fenitrothion	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		63	Fenpropathrin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		64	Fensulfothion （Fensulfothion、Fensulfothion-Oxon、Fensulfothion-Sulfone、Fensulfothion-Oxon-Sulfone）	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		65	Fenthion （Fenthion，Fenthion Oxon，Fenthion-Sulfone，Fenthion	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Sulfoxide，		LC-MS/MS）	
		66	Fenvalerate	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		67	Flucythrinate	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		68	Tau-Fluvalinate	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		69	ε-BHC	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					MS/MS）	
		70	Malathion，Malaoxon	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		71	Mecarbam	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		72	Methacrifos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		73	Methidathion	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		74	Methoxychlor	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		75	Mirex	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		76	Pendimethalin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		77	Pentachloranisole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		78	Permethrin	ChP ChP2025 Vol IV general notices 2341	general	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					notices 2341 Mthod IV（only GC-MS/MS）	
		79	Phosalone	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		80	Phosmet	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		81	Piperonyl Butoxide	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		82	Pirimiphos-Ethyl	ChP ChP2025 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					2341 Mthod IV（only LC-MS/MS）	
		83	Pirimiphos-Methyl（Pirimiphos-Methyl、N-Desethyl-Pirimiphos-Methyl）	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		84	Procymidone	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		85	Profenofos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		86	Prothiofos	ChP ChP2025 Vol IV general notices 2341	general notices 2341	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Mthod IV（only GC-MS/MS）	
		87	pyrethrins	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		88	quinalphos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		89	Pentachloroaniline	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		90	Methyl-pentachlorophrnyl sulfide	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					（only GC-MS/MS）	
		91	octachlorodipropyl ether	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		92	tecnazene	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		93	tetradifon	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		94	vinclozolin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					GC-MS/MS）	
		95	(RS)-1,2-Dibromo-3-chloropropane	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		96	bromothalonil	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		97	etridiazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		98	trifluralin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					MS/MS）	
		99	molinate	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		100	captan	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		101	diphenylamine	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		102	atrazine	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		103	pyrimethanil	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		104	dichlofenthion	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		105	2,4-D-butyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		106	acetochlor	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		107	propisochlor	ChP ChP2025 Vol IV general notices 2341	general	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					notices 2341 Mthod IV （only GC-MS/MS）	
		108	chlorothalonil	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		109	propanil	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		110	tolclofos-methyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		111	butralin	ChP ChP2025 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					2341 Mthod IV（only GC-MS/MS）	
		112	ametryn	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		113	metolachlor	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		114	metalaxyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		115	triadimefon	ChP ChP2025 Vol IV general notices 2341	general notices 2341	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Mthod IV（only GC-MS/MS）	
		116	thiobencarb	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		117	allethrin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		118	flumetralin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		119	isofenphos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					（only GC-MS/MS）	
		120	cyprodinil	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		121	triadimenol	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		122	butachlor	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		123	dimethachlone	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					GC-MS/MS）	
		124	pretilachlor	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		125	oxadiazon	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		126	thifluzamide	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		127	fluazifop-butyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					MS/MS）	
		128	flutolanil	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		129	chlorfenapyr	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		130	diniconazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		131	picoxystrobin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		132	isoprothiolane	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		133	fludioxonil	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		134	propiconazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		135	RH5849	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		136	bifenthrin	ChP ChP2025 Vol IV general notices 2341	general	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					notices 2341 Mthod IV （only GC-MS/MS）	
		137	benalaxyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		138	triazophos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		139	oxadixyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		140	acrinathrin	ChP ChP2025 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					2341 Mthod IV（only GC-MS/MS）	
		141	iprodione	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		142	phenothrin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		143	tetramethrin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		144	hexazinone	ChP ChP2025 Vol IV general notices 2341	general notices 2341	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Mthod IV（only GC-MS/MS）	
		145	cyhalofop-butyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		146	fenoxaprop-P-ethyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		147	etofenprox	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		148	quizalofop-P-ethyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					（only GC-MS/MS）	
		149	boscalid	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		150	difenoconazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		151	azoxystrobin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only GC-MS/MS）	2026-07-28
		152	propamocarb hydrochloride	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					LC-MS/MS）	
		153	pymetrozine	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		154	dinotefuran	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		155	nitenpyram	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		156	carbendazim	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					MS/MS）	
		157	Formamidine	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		158	thiabendazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		159	dicrotophos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		160	thiamethoxam	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		161	trichlorfon	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		162	flonicamid	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		163	imidacloprid	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		164	clothianidin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		165	acetamiprid	ChP ChP2025 Vol IV general notices 2341	general	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					notices 2341 Mthod IV （only LC-MS/MS）	
		166	tricyclazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		167	flumetsulam	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		168	cymoxanil	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		169	ethiofencarb	ChP ChP2025 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					2341 Mthod IV （only LC-MS/MS）	
		170	thiacloprid	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		171	nicosulfuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		172	sulfoxaflor	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		173	thidiazuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method		Note	Effective Date
		№	Item/ Parameter				
						Mthod IV（only LC-MS/MS）	
		174	difenzoquat	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		175	simazine	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		176	mesotrione	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		177	simetryn	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					（only LC-MS/MS）	
		178	metolcarb	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		179	thifensulfuron-methyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		180	thiophanate-methyl	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		181	imazalil	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					LC-MS/MS）	
		182	ethaboxam	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		183	isoproturon	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		184	diuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		185	isoprocarb	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					MS/MS）	
		186	bensulfuron-methyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		187	flumorph	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		188	tribenuron-methyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		189	Clomazone	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		190	dimethomorph	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		191	halofenozide	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only GC-MS/MS）	2026-07-28
		192	paclobutrazol	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		193	prometryn	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		194	fenobucarb	ChP ChP2025 Vol IV general notices 2341	general	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					notices 2341 Mthod IV （only LC-MS/MS）	
		195	pyrazosulfuron-ethyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		196	diethofencarb	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		197	fomesafen	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		198	chlorimuron-ethyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					2341 Mthod IV（only LC-MS/MS）	
		199	uniconazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		200	myclobutanil	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		201	halosulfuron-methyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		202	epoxiconazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method		Note	Effective Date
		№	Item/ Parameter				
						Mthod IV（only LC-MS/MS）	
		203	mefenacet	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		204	spirotetramat	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		205	fenhexamid	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		206	mandipropamid	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method		Note	Effective Date
		№	Item/ Parameter				
						（only LC-MS/MS）	
		207	tebuconazole	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		208	spinosad	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		209	flusilazole	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		210	methoxyfenozide	ChP ChP2025 Vol IV	general notices 2341	general notices 2341 Mthod IV （only	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					LC-MS/MS）	
		211	diflubenzuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		212	tridemorph	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		213	hexaconazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		214	iprobenfos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					MS/MS）	
		215	prochloraz	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		216	napropamide	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		217	bifenazate	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		218	flufenacet	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		219	penconazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		220	tebufenozide	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		221	rotenone	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		222	spinetoram	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		223	carfentrazone-	ChP ChP2025 Vol IV general notices 2341	general	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			ethyl(D)		notices 2341 Mthod IV （only LC-MS/MS）	
		224	edifenphos	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		225	triflumuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		226	emamectin benzoate(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		227	cyazofamid	ChP ChP2025 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					2341 Mthod IV（only LC-MS/MS）	
		228	triflumizole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		229	clodinafop-propargyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		230	pyraclostrobin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		231	clofentezine	ChP ChP2025 Vol IV general notices 2341	general notices 2341	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Mthod IV（only LC-MS/MS）	
		232	zoxamide	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		233	pencycuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		234	phoxim	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		235	haloxyfop-P-methyl(D)	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					（only LC-MS/MS）	
		236	diflufenican	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		237	indoxacarb	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		238	trifloxystrobin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		239	clethodim	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					LC-MS/MS）	
		240	benfuracarb	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		241	oxaziclomefone	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		242	buprofezin	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		243	pyriproxyfen	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					MS/MS）	
		244	lactofen	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		245	flufenoxuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		246	hexythiazox	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		247	bromadiolone	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		248	fenpyroximate	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		249	chlorfluazuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		250	etoxazole	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		251	propargite	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV（only LC-MS/MS）	2026-07-28
		252	tri-allate	ChP ChP2025 Vol IV general notices 2341	general	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					notices 2341 Mthod IV （only LC-MS/MS）	
		253	diafenthiuron	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		254	amitraz	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		255	pyridaben	ChP ChP2025 Vol IV general notices 2341	general notices 2341 Mthod IV （only LC-MS/MS）	2026-07-28
		256	abamectin	ChP ChP2025 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					2341 Mthod VI	
		257	chlorothalonil	ChP ChP2026 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		258	difenoconazole	ChP ChP2027 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		259	propiconazole	ChP ChP2028 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		260	pymetrozine	ChP ChP2029 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		261	imidacloprid	ChP ChP2030 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		262	pyraclostrobin	ChP ChP2031 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		263	tebufenozide	ChP ChP2032 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		264	pyrethrins	ChP ChP2033 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		265	diazinon	ChP ChP2034 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		266	pyridaben	ChP ChP2035 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		267	boscalid	ChP ChP2036 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		268	acetamiprid	ChP ChP2037 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		269	chlorpyrifo	ChP ChP2038 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		270	carbendazim	ChP ChP2039 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		271	fluazinam	ChP ChP2040 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					2341 Mthod VI	
		272	flusilazol	ChP ChP2041 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		273	epoxiconazole	ChP ChP2042 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		274	fludioxonil	ChP ChP2043 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		275	hexaconazole	ChP ChP2044 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		276	cypermethrin and beta-cypermethrin	ChP ChP2045 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		277	cyhalothrin and lambda-cyhalothrin	ChP ChP2046 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		278	emamectin benzoate	ChP ChP2047 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		279	metalaxyl and metalaxyl-M	ChP ChP2048 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		280	cyprodinil	ChP ChP2049 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		281	pyrimethanil	ChP ChP2050 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		282	kresoxim-methyl	ChP ChP2051 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		283	fenvalerate and esfenvalerate	ChP ChP2052 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		284	thifluzamide	ChP ChP2053 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		285	propamocarb and propamocarb hydrochloride	ChP ChP2054 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		286	tridemorph	ChP ChP2055 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					2341 Mthod VI	
		287	tebuconazole	ChP ChP2056 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		288	dimethomorph	ChP ChP2057 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		289	fenpyroximate	ChP ChP2058 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		290	dithiocarbamates	ChP ChP2059 Vol IV general notices 2341	general notices 2341 Mthod VII	2026-07-28
		291	paclobutrazol	ChP ChP2060 Vol IV general notices 2341	general notices 2341 Mthod VI	2026-07-28
		292	methidathion	ChP ChP2061 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		293	2,4-D –Butylate	ChP ChP2062 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		294	methomyl	ChP ChP2063 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		295	omethoate	ChP ChP2064 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		296	dimethoate	ChP ChP2065 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		297	acephate	ChP ChP2066 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		298	chlorobenzilate	ChP ChP2067 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		299	octachlorodipropyl ether	ChP ChP2068 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		300	sulfluramid	ChP ChP2069 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		301	chlordane(cis-chlordane, trans-	ChP ChP2070 Vol IV general notices 2341	general notices	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			chlordane and oxy-chlordane)		2341 Mthod V	
		302	mirex	ChP ChP2071 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		303	hexachlorobenzene	ChP ChP2072 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		304	heptachlor(heptachlor, heptachlor-exo-epoxide and heptachlo-endo-epoxide	ChP ChP2073 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
		305	endrin	ChP ChP2074 Vol IV general notices 2341	general notices 2341 Mthod V	2026-07-28
Biological product						
1	Biological product	1	virus titration(plaque assay)	ChP2025 VolⅢ,Monographs		2026-07-28
		2	Identity(plaque assay)	ChP2025 VolⅢ,Monographs		2026-07-28
		3	Determination of 2-phenoxyethanol content	ChP2025 VolⅢ,Monographs		2026-07-28
		4	Host residue	ChP2025 Vol Ⅲ/Ⅳ，general rule （3414）		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			protein(ELISA)			
		5	Residual carbodiimide content	ChP2025 Vol Ⅲ/Ⅳ，general rule （3206）		2026-07-28
		6	O-acetyl content	ChP2025 Vol Ⅲ/Ⅳ，general rule （3117）		2026-07-28
		7	pH	ChP2025 Vol Ⅲ/Ⅳ，general rule （0631）		2026-07-28
		8	protein content (immunodiffusion method)	ChP2025 VolⅢ,Monographs		2026-07-28
		9	Efficacy (Skin test)	ChP2025 VolⅢ,Monographs		2026-07-28
		10	Analysis of amino acid	Imported drug registration standards JS20200047		2026-07-28
		11	Purity of albumin	ChP2025 VolⅢ,Monographs		2026-07-28
		12	Diphtheria antibody	ChP2025 Vol Ⅲ/Ⅳ，general rule （3513）		2026-07-28
		13	Determination of phenol content	ChP2025 Vol Ⅲ/Ⅳ，general rule （3113）		2026-07-28
				Imported drug registration standards JS20210014		2026-07-28
				Imported drug registration standards JS20210015		2026-07-28
		14	disintegration test	ChP2025 Vol Ⅲ/Ⅳ，general rule （0921）		2026-07-28
		15	virus titration	ChP2025 VolⅢ,Monographs		2026-07-28
				National Drug Standards WS4-(ZB-070)-2010		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Virus Titration (Cytopathic)	ChP2025 VolⅢ,Monographs		2026-07-28
				Drug registration standards YBS00482021		2026-07-28
				Drug registration standards YBS00312015		2026-07-28
				Drug registration standards YBS00252021		2026-07-28
		17	virus titration(micro plate CPE)	ChP2025 VolⅢ,Monographs		2026-07-28
				National Drug Standards WS4-(ZB-004)-2011		2026-07-28
		18	Test for reversion of neurovirulence in mice	ChP2025 VolⅢ,Monographs		2026-07-28
		19	Identity(single radial immunodiffusion)	ChP2025 VolⅢ,Monographs		2026-07-28
		20	Virus inactivated validation	ChP2025 VolⅢ,Monographs		2026-07-28
				Drug registration standards YBS00282016		2026-07-28
		21	Test for Adventitious virus(Cell culture method)	ChP2025 Vol Ⅲ， general rule (3302)		2026-07-28
		22	Determination of insoluble particles	ChP2025 Vol Ⅲ/Ⅳ， general rule （0903）		2026-07-28
				EP 12.1 2.9.19particulate contamination sub-visible particles		2026-07-28
		23	Residual solvents	ChP2025 Vol Ⅲ/Ⅳ， general rule (0861)		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		24	Purity(HPLC method)	ChP2025 Vol Ⅲ，general rule (0512)		2026-07-28
		25	Test for the absence of contaminating organisms	ChP2025 VolⅢ,Monographs （1101）		2026-07-28
		26	Residue bacteria protein	ChP 2025 Vol Ⅲgeneral rule (3412)		2026-07-28
				ChP 2025 Vol Ⅲgeneral rule (3413)		2026-07-28
				ChP 2025 Vol Ⅲgeneral rule (3414)		2026-07-28
		27	Potency of monoclonal antibody	ChP2025 Vol Ⅲ/Ⅳ，general rule （3531）		2026-07-28
				Drug registration standards		2026-07-28
		28	Protein purity(SDS PAGE)	ChP2025 Vol Ⅲ，general rule (0541)		2026-07-28
		29	Protein purity(HPLC method)	ChP2025 Vol Ⅲ，general rule (0512)		2026-07-28
		30	Protein molecular weight (SDS PAGE)	ChP2025 Vol Ⅲ，general rule (0541)		2026-07-28
		31	Protein content	ChP2025 Vol Ⅲ，general rule (0731)		2026-07-28
		32	Protein content (TCA-Lowry method)	Imported drug registration standards JS20040032		2026-07-28
		33	Protein nitrogen content	Imported drug registration standards JS20190028		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Imported drug registration standards JS20190020		2026-07-28
		34	protein content (Lowry method)	ChP2025 Vol Ⅲ/Ⅳ，general rule （0731）		2026-07-28
		35	protein content (UV method)	ChP2025 Vol Ⅲ/Ⅳ，general rule （0731）		2026-07-28
		36	Nitrogen content	ChP2025 Vol Ⅲ/Ⅳ，general rule (0704)		2026-07-28
		37	Isoelectric focusing electrophoresis	ChP2025 Vol Ⅲ，general rule (0541)		2026-07-28
		38	Test for reversion to toxicity (pertussis vaccine)	ChP2025 VolⅢ,Monographs		2026-07-28
		39	Test for reversion to toxicity (toxoid)	ChP2025 VolⅢ,Monographs		2026-07-28
		40	Molecular size distribution	ChP2025 Vol Ⅲ/Ⅳ，general rule (3419)		2026-07-28
		41	polyscharide content	ChP2025 Vol Ⅲ/Ⅳ，general rule (3103)		2026-07-28
		42	polysaccharide content	ChP2025 VolⅢ,Monographs		2026-07-28
		43	polyscharide content	ChP2025 VolⅢ,Monographs		2026-07-28
				Drug registration standards YBS00222025		2026-07-28
				Drug registration standards YBS00232025		2026-07-28
				Drug registration standards YBS00392019		2026-07-28
				Drug registration standards YBS00012018		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Drug registration standards YBS00352025		2026-07-28
				Imported drug registration standards JS20140065		2026-07-28
				Imported drug registration standards JS20200058		2026-07-28
		44	molecular size test (Vi-PS)	ChP2025 Vol Ⅲ/Ⅳ，general rule （3420）		2026-07-28
		45	Distribution of molecular size	ChP2025 Vol Ⅲ/Ⅳ，general rule （3121）		2026-07-28
				ChP2025 Vol Ⅲ/Ⅳ，general rule （3122）		2026-07-28
		46	Phenol content	Imported drug registration standards JS20200054		2026-07-28
		47	Virurs titer(Cell culture method)	Adenov titration assay NIFDC-SOP-B-T-0580		2026-07-28
		48	moisture content (weight loss method)	ChP2025 Vol Ⅲ/Ⅳ，general rule (0831)		2026-07-28
		49	content in high molecular weight conjugate	ChP2025 Vol Ⅲ/Ⅳ，general rule (3119)		2026-07-28
		50	total solids	ChP2025 Vol Ⅲ/Ⅳ，general rule （3101）		2026-07-28
		51	Hypersensitive test/Sensitization test	ChP2025 Vol Ⅳ，general rule （1147）		2026-07-28
		52	Content（HPLC）	ChP2025 Vol Ⅲ/Ⅳ，general rule （0512）		2026-07-28
				ChP2025 Vol Ⅲ/Ⅳ，general rule （3124）		2026-07-28

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		№	Item/ Parameter			
		53	Analysis of nucleotide	Imported drug registration standards JS20200047		2026-07-28
		54	nucleic acid content	ChP2025 Vol Ⅲ/Ⅳ，general rule （0401）		2026-07-28
		55	polysaccharide content(ribose method)	ChP2025 Vol Ⅲ/Ⅳ，general rule (3421)		2026-07-28
		56	bacteria counting	ChP2025 VolⅢ,Monographs		2026-07-28
		57	Determination of metacresol content	ChP2025 Vol Ⅲ/Ⅳ，general rule （3144）		2026-07-28
		58	Test for the absence of contaminating organisms（Animal Test）	ChP2025 Vol Ⅲ， monographs		2026-07-28
		59	Identity test（ acid-fast stained smear）	ChP2025 Vol Ⅲ， monographs		2026-07-28
		60	Identity test	ChP2025 VolⅢ,Monographs		2026-07-28
				Drug registration standards YBS01402011		2026-07-28
				Drug registration standards YBS00482021		2026-07-28
				Drug registration standards YBS00312015		2026-07-28
				Drug registration standards YBS00252021		2026-07-28
		61	Identity test (Immunodot)	ChP2025 Vol Ⅲ/Ⅳ，general rule （3402）		2026-07-28
		62	Identity (SDS-PAGE method)	ChP2025 Vol Ⅲ/Ⅳ，general rule （3404）		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		63	Identity (immunodiffusion method)	ChP2025 Vol Ⅲ/Ⅳ，general rule （3403）		2026-07-28
		64	Identity (WB method)	ChP2025 Vol Ⅲ/Ⅳ，general rule （3401）		2026-07-28
		65	Identity test (Immunogenicity)	ChP2025 VolⅢ,Monographs		2026-07-28
		66	Identity test (Intracerebral neutralization test)	ChP2025 VolⅢ,Monographs		2026-07-28
		67	identity test	ChP2025 VolⅢ,Monographs		2026-07-28
		68	Identity test (Gel immunoprecipitation test)	ChP2025 VolⅢ,Monographs		2026-07-28
		69	Identity test (Skin test)	ChP2025 VolⅢ,Monographs		2026-07-28
		70	Identity test of vaccine, live （Plaque method）	ChP2025 VolⅢ,Monographs		2026-07-28
		71	identity test	Imported drug registration standards JS20140079		2026-07-28
		72	Identity test (Neutralization test)	ChP2025 VolⅢ,Monographs		2026-07-28
		73	Identification （cell culture）	ChP2025 VolⅢ,Monographs		2026-07-28
				National Drug Standards WS4-(ZB-004)-2011		2026-07-28
		74	Identity test (Flocculation test)	ChP2025 VolⅢ,Monographs		2026-07-28

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		№	Item/ Parameter			
		75	T cell proliferation	ChP2025 VolⅢ,Monographs		2026-07-28
		76	Determination of Residual Polysorbate 80 Content(Colorimetry Method)	ChP2025 Vol Ⅲ，general rule （3203）		2026-07-28
		77	Residual PEG (colorimetric method)	ChP2025 Vol Ⅲ，general rule (3202)		2026-07-28
		78	Inspection for morphology and colony of bacilli	ChP2025 VolⅢ,Monographs		2026-07-28
		79	Bacteria/Yeast/Virus Seed Identification（ELISA）	ChP 2025 Vol Ⅲ monograph		2026-07-28
		80	Bacteria/Yeast/Virus seed identification (Nucleic Acid Electrophoresis)	ChP 2025 Vol Ⅲ monograph		2026-07-28
		81	Identification of virus seed/strain (sequencing)	Drug registration standard WS4-(ZB-004)-2011		2026-07-28
		82	Identification of bacteria	Bergey's Manual of Determinative Bacteriology,ChP2025 VolⅢ,Monographs		2026-07-28
		83	Potency test for antitoxins (Animal test)	ChP2025 Vol Ⅲ/Ⅳ，general rule （3507）		2026-07-28
				ChP2025 Vol Ⅲ/Ⅳ，general rule （3508）		2026-07-28
				ChP2025 Vol Ⅲ/Ⅳ，general rule （3509）		2026-07-28

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		№	Item/ Parameter			
				ChP2025 Vol Ⅲ/Ⅳ，general rule （3510)		2026-07-28
		84	Determination of glycin content	ChP2025 VolⅢ		2026-07-28
		85	Antibiotic residue （ELISA)	ChP2025 VolⅢ,Monographs		2026-07-28
				Drug registration standards YBS00282015		2026-07-28
		86	Test for purity of antisera/antitoxins	ChP2025 VolⅢ,Monographs		2026-07-28
		87	Ag and Ab content (ELISA method)	ChP2025 VolⅢ,Monographs		2026-07-28
		88	Test fo Visible Particles	ChP2025 Vol Ⅲ，general rule （0904）		2026-07-28
				EP 12.1 2.9.20.PARTICULATE CONTAMINATION: VISIBLE PARTICLES		2026-07-28
		89	Potency test for rabies antiserum (MNT)	ChP2025 Vol Ⅲ/Ⅳ，general rule (3512) 1		2026-07-28
		90	Potency test for rabies antiserum (RIFFT)	ChP2025 Vol Ⅲ/Ⅳ，general rule (3512) 2		2026-07-28
		91	Potecy test for rabies vaccine (NIH)	ChP2025 Vol Ⅲ/Ⅳ，general rule (3503)		2026-07-28
		92	Test for purity of toxoid	ChP2025 VolⅢ,Monographs		2026-07-28
		93	Flocculation unit test of toxoid	ChP2025 Vol Ⅲ/Ⅳ，general rule (3506)		2026-07-28
		94	Potency test for toxoid	ChP2025 Vol Ⅲ/Ⅳ，general rule (3504)		2026-07-28

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		№	Item/ Parameter			
				ChP2025 Vol Ⅲ/Ⅳ，general rule (3505)		2026-07-28
		95	KPI test	Imported drug registration standards JS20200047		2026-07-28
		96	Determination of Particle Size Distribution	ChP2025 Vol Ⅲ，general rule （0982）		2026-07-28
		97	Analysis of phosphorus	Imported drug registration standards JS20200047		2026-07-28
		98	Determination of ammonium sulfate content	ChP2025 Vol Ⅲ/Ⅳ，general rule (3104)		2026-07-28
		99	NaCl content	ChP2025 Vol Ⅲ/Ⅳ，general rule (3107)		2026-07-28
		100	saccharide and saccharide alcohols （HPLC）	ChP2025 VolⅢ,Monographs		2026-07-28
		101	Immunogenicity (ELISA)	ChP2025 VolⅢ,Monographs		2026-07-28
				National Drug Standards WS_4-(ZB-004)-2011		2026-07-28
		102	immunogenicity	Drug registration standards YBS00282016		2026-07-28
		103	Concentrations	ChP2025 Vol Ⅲ， monographs		2026-07-28
		104	Aluminum	ChP 2025 Vol Ⅲgeneral rule (3106)		2026-07-28
				ChP 2025Vol Ⅳ 0411		2026-07-28
				Imported drug registration standards JS20190028		2026-07-28

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				Imported drug registration standards JS20190020		2026-07-28
				ChP 2025Vol Ⅳ 0412		2026-07-28
				Imported drug registration standards 20210014		2026-07-28
				Imported drug registration standards 20210015		2026-07-28
		105	residual cyanide content	ChP 2025 Vol Ⅲ/Ⅳgeneral rule (0806)		2026-07-28
		106	residual DOC content	Drug registration standards YBS10282020		2026-07-28
		107	Thermal stability test	ChP2025 VolⅢ,Monographs		2026-07-28
				Drug registration standards YBS00282015		2026-07-28
		108	Test for safety and identify of botulinum toxin	Imported drug registration standards JS20120050		2026-07-28
		109	Lactose content	Imported drug registration standards JS20190022		2026-07-28
		110	Determination of osmolality	ChP2025 Vol Ⅲ/Ⅳ，general rule (0632)		2026-07-28
		111	Pyrogen	ChP 2025 Vol III/IV general rule (1142)		2026-07-28
				EP 11.4 <2.6.8>（2023）		2026-07-28
				USP -NF <151>（ 01-May-2017）		2026-07-28
		112	moistrue content(volumetric method)	ChP2025 Vol Ⅲ/Ⅳ，general rule (0832)		2026-07-28

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		№	Item/ Parameter			
		113	Paptide Mapping Analysis（Trypsin Cleavage- Reversre Phase HPLC Method）	ChP 2025 Vol Ⅲgeneral rule （3405）		2026-07-28
		114	in Vitro Relative Potency	ChP 2025Vol Ⅲgeneral rule （3501）		2026-07-28
		115	Test for special toxicity	ChP2025 Vol Ⅲ，monograph		2026-07-28
		116	sialic acid content	ChP 2025 Vol Ⅲ/Ⅳgeneral rule,Drug registration standards (3102)		2026-07-28
		117	Appearance	ChP 2025 Vol Ⅲ monograph		2026-07-28
		118	Host residue DNA	ChP2025 Vol Ⅲ/Ⅳ，general rule (3407)		2026-07-28
		119	The limits of contaminated bacterias	ChP 2025 Vol III/IV general rule (1105)		2026-07-28
				ChP 2025 Vol III/IV general rule (1106)		2026-07-28
		120	Thermostability	National Drug Standards WS4-(ZB-070)-2010		2026-07-28
		121	sterility (membrane filtration method)	ChP 2025 Vol III/IV general rule (1101)		2026-07-28
		122	sterility (direct inoculation method)	ChP 2025 Vol III/IV general rule (1101)		2026-07-28
		123	Glutaric dialdehyde content	ChP 2025 Vol III/IV general rule (3204)		2026-07-28
		124	Absorbance（UV-Spectrophotometry）	ChP 2025Vol Ⅲgeneral rule （0401）		2026-07-28

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		№	Item/ Parameter			
		125	bacterial form and purity	ChP 2025 Vol III		2026-07-28
		126		ChP 2025 Vol III		2026-07-28
				ChP 2025 Vol VI 1143		2026-07-28
				ChP 2025 Vol Ⅳ general rule (9251)		2026-07-28
				EP 12.1 <2.6.14>（2026）		2026-07-28
				USP -NF <85>（2020）		2026-07-28
				JP 18 <4.01>（2021）		2026-07-28
		127	Specific toxicity test (pertussis)	ChP2025 Vol Ⅲ，monograph		2026-07-28
		128	Specific toxicity test (toxoid)	ChP2025 Vol Ⅲ，monograph		2026-07-28
		129	Test for calf serum	ChP 2025 Vol Ⅲ general rule （3604）		2026-07-28
		130	serological test for bacteria	ChP 2025 Vol III，monographs		2026-07-28
		131	residual ethanol content	ChP 2025Vol Ⅲ/Ⅳ general rule (3201)		2026-07-28
		132	Antigen expression	ChP 2025 Vol Ⅲ general rule （0731）		2026-07-28
		133	Abnormal toxicity	ChP 2025 Vol III/IV general rule (1141)		2026-07-28
		134	free polyscharide content	ChP 2025 Vol Ⅲ/Ⅳ general rule(3119)		2026-07-28
				ChP 2025 Vol Ⅲ/Ⅳ general rule（0401）		2026-07-28

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		№	Item/ Parameter			
				ChP 2025 Vol Ⅲ/Ⅳgeneral rule(0513)		2026-07-28
				ChP 2025 Vol Ⅲ monograph		2026-07-28
				Drug registration standardsYBS00392019		2026-07-28
				Drug registration standardsYBS00012018		2026-07-28
				Import drug registration standardsJS20140065		2026-07-28
		135	Free Formaldehyde (colorimetric method)	ChP 2025 Vol Ⅲgeneral rule (3207)		2026-07-28
		136	contaminated bacterias test	ChP 2025 Vol III，monographs		2026-07-28
		137	Thimerosal content	ChP2025 Vol Ⅲ/Ⅳ，general rule (3115)		2026-07-28
		138	Ovalbumin content	ChP2025 Vol Ⅲ， monographs		2026-07-28
		139	Protein Content（catalysed oxidising pyrolysis and chemiluminescence）	Import drug registration standards JS20210014		2026-07-28
				Imported drug registration standards JS20210015		2026-07-28
		140	residual bovine serum albumin	ChP2025 Vol Ⅲ/Ⅳ，general rule (3411)		2026-07-28
		141	sucrose content	ChP 2025Vol Ⅳgeneral rule (0621)		2026-07-28
		142	Test for abirritation potency	Registration Standards JS20200047		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		143	Test for Mycoplasma	ChP 20250 Vol Ⅲgeneral rule （3301）		2026-07-28
				EP12.2 （2.6.7） Mycoplasma nucleic acid detection (NAT method)		2026-07-28
		144	Filling	ChP2025 VolⅢ/Ⅳ General rule (0100)		2026-07-28
		145	Content uniformity	ChP20205 VolⅢ/Ⅳ General rule (0100)		2026-07-28
		146	UV spectrum test	ChP 2025 Vol III/IV general rule (0401)		2026-07-28
		147	Analysis of ultraviolet absorption spectroscopy	ChP2025 Vol Ⅲ/Ⅳ，general rule (0401)		2026-07-28
		148	Test for dextrose concentration （Anthrone method）	ChP2010 VolⅢ， sup2		2026-07-28
		149	Test for minimum filling	ChP2025 VolⅢ/Ⅳ General rule （0942）		2026-07-28
		150	Haemagglutinin content	ChP2025 Vol Ⅲ， monographs		2026-07-28
		151	Potency test (animal method)	Human papillomavirus vaccine in vivo potency assay NIFDC-SOP-B-T-0545		2026-07-28
		152	Potency test (Serum antibody)	ChP2025 Vol Ⅲ， monographs		2026-07-28
		153	Potency test (cell method)	Human papillomavirus neutralization assay NIFDC-SOP-B-T-0568		2026-07-28
		154	Potency test (ELISA)	National Drug Standards YBS01402011		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		155	Potency (in-vitro)	ChP 2025Vol Ⅲgeneral rule (3501)		2026-07-28
				ChP 2025Vol Ⅲgeneral rule (3502)		2026-07-28
		156	Identity test（multi-PCR）	ChP2025 Vol Ⅲ， monographs		2026-07-28
				Imported drug registration standards		2026-07-28
		157	NACL content Total Chlorines Titration	Imported drug registration standards JS20210027		2026-07-28
		158	Test for the absence of contaminating organisms（phage bacteriolytic test）	ChP2025 Vol Ⅲ， monographs		2026-07-28
		159	test for Mycobacteria （culture）	ChP2025 Vol Ⅲ， monographs		2026-07-28
		160	Capillary gel electrophoresis (reduced and none reduced CE-SDS)	ChP2025VolⅢ/Ⅳ General rule （3127）		2026-07-28
		161	Allergen biological activity （UNICAP）	Imported drug registration standards JS20210014		2026-07-28
				Imported drug registration standards，Drug registration standards， National food and drug administration standards JS20210015		2026-07-28
				Drug registration standards JS20190028		2026-07-28
				National food and drug administration standards WS4-（S-012)-2010Z		2026-07-28

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		№	Item/ Parameter			
				Imported drug registration standards JS20190028		2026-07-28
				Imported drug registration standards JS20190020		2026-07-28
		162	Allergen biological activity（ELISA Inhibition）	Imported drug registration standards JS20210014		2026-07-28
				Imported drug registration standards JS20210015		2026-07-28
				Imported drug registration standards JS20210027		2026-07-28
		163	Allergen identification	ChP 2025 Vol Ⅳgeneral rule 0512		2026-07-28
				Imported drug registration standards JS20200049 Method 1		2026-07-28
				ChP 2025Vol Ⅳ general rule 0521		2026-07-28
				Imported drug registration standards JS20200049 Method 2		2026-07-28
		164	Allergen Assay	ChP 2025 Vol Ⅳgeneral rule 0512		2026-07-28
				Imported drug registration standards JS20200049 Method 1		2026-07-28
				ChP 2025 Vol Ⅲgeneral rule 0405		2026-07-28
				Imported drug registration standards JS20200049Method 2		2026-07-28
				ChP 2025Vol Ⅳ general rule 0521		2026-07-28
				Imported drug registration standards JS20200049Method 3		2026-07-28
		165	Antibiotic resistance	ChP2025VolⅢ,Monographs		2026-07-28

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		№	Item/ Parameter			
		166	Electron microscopy	ChP2025 VolⅢ,Monographs		2026-07-28
		167	Expression level	ChP2025 VolⅢ,Monographs		2026-07-28
		168	Plasmid examination	ChP2025 VolⅢ,Monographs		2026-07-28
		169	Test for residual virulence	ChP2025 VolⅢ,Monographs		2026-07-28
		170	Tests for dissociation	ChP2025 VolⅢ,Monographs		2026-07-28
		171	Serological test	ChP2025 VolⅢ,Monographs		2026-07-28
		172	Cultural characteristics	ChP2025 VolⅢ,Monographs		2026-07-28
		173	Microscopic examination of stained smears	ChP2025 VolⅢ,Monographs		2026-07-28
		174	Determination of residual polysorbate 20 content	Drug registration standards		2026-07-28
		175	Test for virulence	ChP2025 VolⅢ,Monographs		2026-07-28
		176	sedimentation rate	ChP2025 VolⅢ,Monographs		2026-07-28
		177	test for viability	ChP2025VolⅢ,Monographs		2026-07-28
		178	test for Antitumor activity	ChP2025 VolⅢ,Monographs		2026-07-28
		179	test for content of CpG	Standard Operation Procedure NIFDC-SOP-B-T-6077		2026-07-28

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		№	Item/ Parameter			
		180	Hemagglutination inhibition	ChP 2025 Vol III		2026-07-28
		181	Virus identity(RFLP)	ChP 2025 Vol III		2026-07-28
		182	Antibody Titer Detection(FAMA)	ChP 2025 Vol III		2026-07-28
		183	Antibody Titer Detection(pseudovirus neutralization)	ChP 2025 Vol III		2026-07-28
		184	Antibody Titer Detection(micro plate neutralization)	ChP 2025 Vol III		2026-07-28
		185	Determination of residual exogenous DNA	ChP2025 Vol Ⅲ，general rule (3407)		2026-07-28
		186	Detection of target antigen expression	ChP2025 VolⅢ,Monographs		2026-07-28
		187	Detection of RCA	ChP2025 VolⅢ,Monographs		2026-07-28
		188	Virus Titration (Animal)	ChP2025 VolⅢ,Monographs		2026-07-28
		189	Immunogenicity (Animal)	ChP2025 VolⅢ,Monographs		2026-07-28
		190	Virus inactivated validation （Animal）	ChP2025 VolⅢ,Monographs		2026-07-28
		191	Reverse transcriptase	ChP 2025, Part III，General Principles 0234，Regulation on preparation of animal cell substrates for the production of biological products		2026-07-28

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		№	Item/ Parameter			
		192	Viral nucleic acid（qPCR）	human immunodeficiency virus type 1 RNA detection assay NIFDC-SOP-B-T-0564		2026-07-28
		193	Capillary zone electrophoresis (CZE)	ChP 2025 Vol Ⅲ general rule (0542)		2026-07-28
		194	Hydrophobic chromatography (HIC - HPLC)	ChP 2025 Vol Ⅲ general rule (0512)		2026-07-28
		195	Ion exchange chromatography（IEC-HPLC）	ChP 2025 Vol Ⅲ general rule (0512)		2026-07-28
		196	Reversre Phase chromatography（RP-HPLC）	ChP 2025 Vol Ⅲ general rule (0512)		2026-07-28
		197	Capillary isoelectric focusing electrophoresis（cIEF）	ChP 2025 Vol Ⅲ general rule (0542)		2026-07-28
		198	imaged Capillary isoelectric focusing electrophoresis（iCIEF）	ChP 2025Vol Ⅲ general rule (0542)		2026-07-28
		199	Dissolution time	Dissolution time test of Monoclonal antibody product NIFDC-SOP-B-T-3030		2026-07-28
		200	Color	ChP 2025 Vol Ⅲ general rule (0901)		2026-07-28
				EP 12.1 <2.2.2>		2026-07-28
		201	Clarity	ChP 2025 Vol Ⅲ general rule (0902)		2026-07-28

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		№	Item/ Parameter			
				EP 12.1 <2.2.1>		2026-07-28
		202	N-terminal amino acid sequence	ChP 2025 Vol Ⅲ general rule （0512）		2026-07-28
		203	monocyte activation	General principles of four parts of Chinese Pharmacopoeia 2025 Edition（9301） 9301		2026-07-28
		204		ChP 2025, Part III，General Principles 0234，Regulation on preparation of animal cell substrates for the production of biological products	NEW	2026-07-28
				ChP 2025, Part III, General Principles 0235, Regulation on verification of animal cell of biological products	NEW	2026-07-28
				EP12.1（5.2.3）Cell substrates for the production of vaccines for human use		2026-07-28
				ChP 2025, Part III，General Rule 3429, Immunochemistry, labelling immunochemistry-3 Immunofluorescence Analysis, -5 Flow Cytometry	NEW	2026-07-28
		205		ChP 2025, Part III，General Principles 0234，Regulation on preparation of animal cell substrates for the production of biological products	NEW	2026-07-28
				EP12.1（5.2.3）Cell substrates for the production of vaccines for human use		2026-07-28
		206		ChP 2025, Part III, General Principles 0234, Regulation on preparation of animal cell substrates for the production and verification of biological products.		2026-07-28
				ChP 2025, Part III, General Principles 0235, Regulation on verification of animal cell of biological products	NEW	2026-07-28
				EP12.1（5.2.3）Cell substrates for the production of vaccines for human use		2026-07-28
		207		ChP 2025, Part III, General Principles 0234, Regulation on		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				preparation of animal cell substrates for the production of biological products.		
				EP 12.1（5.2.3） Cell substrates for the production of vaccines for human use		2026-07-28
		208		ChP 2025, Part III，Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-5 Flow Cytometry2. Pharmacopeia General Rule 3429, Immunochemistry, labelling immunochemistry-3 Immunofluorescence Analysis 3. Pharmacopeia General Rule 3429, Immunochemistry, labelling immunochemistry-1 enzyme-linked immuno sorbent assay		2026-07-28
		209		ChP 2025, Part III，Pharmacopeia General Rule 3429, Immunochemistry, labelling immunochemistry-1 enzyme-linked immuno sorbent assay 2. Pharmacopeia General Rule 3429, Immunochemistry, labelling immunochemistry-2 Western blotting 3. 2. Pharmacopeia General Rule 3429, Immunochemistry, labelling immunochemistry-3 Immunofluorescence Analysis 4. 1. Pharmacopoeia General Rule 3429, Immunochemistry, labelling immunochemistry-5 Flow Cytometry		2026-07-28
				ChP 2025, Part III, General Principles 0234, Regulation on preparation of animal cell substrates for the production of biological products.		2026-07-28
				SOP for Teratoma Formation Pluripotency Testing of Pluripotent Stem Cells (HE Staining) &SOP for Teratoma Formation Pluripotency Testing of Pluripotent Stem Cells (in Vivo Inoculation) NIFDC-SOP-B-T-0704，NIFDC-SOP-B-T-0705		2026-07-28
		210		Chp 2025, General Principles 0234, Part III, Regulation on preparation of animal cell substrates for the production of biological products 2. EP11.0，		2026-07-28

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		№	Item/ Parameter			
				01/2018:50203 (5.2.3)Cell substrates for the production of vaccines for human use		
				ChP 2025, Part III, General Principles 0235, Regulation on verification of animal cell of biological products	NEW	2026-07-28
				EP12.1 (5.2.3) Cell substrates for the production of vaccines for human use		2026-07-28
		211		Plasmid DNA Isoforms detection (capillary electrophoresis-capillary gel electrophoresis method, CE-CGE method)Pharmacopoeia General Rule 0542 capillary electrophoresis		2026-07-28
		212		Chp 2025, General Principles 0234, Part III, Regulation on preparation of animal cell substrates for the production of biological products		2026-07-28
				EP12.1（5.2.3）Cell substrates for the production of vaccines for human use		2026-07-28
		213	16S ribosomal RNA gene sequencing of Bacteria	China Pharmacopoeia Vol. Ⅳ General Notices 1021		2026-07-28
		214	Target gene sequencing	method of Sanger sequencing GB/T 34265 2017	Target gene sequencing of Microorganism and Biological product	2026-07-28
		215	Rapid microbiological method for sterility testing	Chinese Pharmacopoeia, 2025 Vol. Ⅳ 9406 Guidelines for Rapid microbiological methods （ respiratory signal detection technology） for cell- based preparations		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		216	Identification for tissue origin of human mesenchymal stem cells	Identification for tissue origin of human mesenchymal stem cells(Statistical Learning method) NIFDC-SOP-B-T-0720	A statistical learning model was established based on gene expression profile data to identified the tissue origin of human mesenchymal stem cells	2026-07-28
		217	Test for integrated gene copy numbers of Gene-modified cells	Test for integrated gene copy numbers of Gene-modified cells by digital PCR (ddPCR) NIFDC-SOP-B-T-0721		2026-07-28
		218	Test for Infectious titer of lentivirus vector	Test for lentivirus vector's infectious titer by digital PCR (ddPCR) NIFDC-SOP-B-T-0722		2026-07-28
		219	Hyaluronidase activity	Hyaluronidase activity Drug registration standards JS20220034		2026-07-28
		220	Potency of monoclonal antibody	Surface Plasmon Resonance Drug registration standards JS20210035		2026-07-28
		221	Protein content	Protein content Drug registration standards		2026-07-28

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		222	protein content (bradford)	ChP 2025 Vol Ⅲ general rule 0731		2026-07-28
				Drug registration standards WS4-(S-012)-2010Z		2026-07-28
		223	histamine content	Imported drug registration standards JS20210027		2026-07-28
		224	histamine content	Drug registration standards YBS00222019		2026-07-28
				ChP 2025 1859 页 Vol II		2026-07-28
		225	Glycerin Content	ChP 2025 133 页 Vol II		2026-07-28
				Drug registration standards YBS00222019		2026-07-28
		226	Antibody detection (OPA/MOPA)	Multiplexed opsonophagocytic killing assay (MOPA) Refer to the WHO recommended methods. WHO Workshop on Standardization of Pneumococcal Opsonophagocytic Assay，Geneva, Switzerland, 25-26 January 2007.		2026-07-28
		227	Detection of polysaccharide and free polysaccharide content by ion-exchange chromatography	ion-exchange chromatography Chinese Pharmacopoeia, 2025 Edition, Part 3，0513		2026-07-28
		228	Telomerase activity detection	Telomerase Activity Detection (RQ-TRAP) Method NIFDC-SOP-B-T-0740		2026-07-28
Biological Products						
1	Biological product	1	Mycoplasma Detection（NAT Method）	Integrated High-Efficiency Mycoplasma Detection（NAT Method） NIFDC-SOP-B-TM-0701		2026-07-28

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2	Biological product	1	Enzyme linked immunosorbent assay for the quantitation of Streptococcus pneumoniae serotype specific IgG	Enzyme linked immunosorbent assay for the quantitation of Streptococcus pneumoniae serotype specific IgG WHO-《Training manual for Enzyme linked immunosorbent assay for the quantitation of Streptococcus pneumoniae serotype specific IgG (Pn PS ELISA).(007sp Version)》		2026-07-28
3	Biological product	1	Serum Bactericidal Assays	Serum Bactericidal Assays WHO Requirements for meningococcal polysaccharid vaccine,Annex 2,TRS NO 594		2026-07-28
4	Biological product	1	Potency of Botulinum Toxin Type A	Enzyme Linked Immunosorbent Assay Pharmacopoeia of the People's Republic of China 2025 Edition Part III General Chapter 3429		2026-07-28
5	Biological product	1	Identification of Multiple Competitive Inhibition of Diphtheria,Tetanus, and Acellular Pertussis Combined Vaccine,Adsorbed	Multiple Competitive Inhibition Assay for Identification of Diphtheria, Tetanus and Acellular pertussis Combined Vaccine, Adsorbed Pharmacopoeia of the People's Republic of China 2025 Edition Part III General Chapter 3432		2026-07-28
Laboratory Animals						
1	Laboratory Animals	1	Salmonella spp.	Laboratory animal-Method for examination of Salmonella spp. GB/T14926.1-2026	only for M、R、H、GP、Rab、D、Mon、treeshrew、Gerbil	2026-07-28

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				Defection methods of Salmonella for animal and animal products NY/T 550-2002	only for Pig	2026-07-28
		2	Yersinia spp.	Laboratory animal-Method for examination of Yersinia spp. GB/T14926.3-2001	only for M、R、H、GP、Rab、D、Mon、	2026-07-28
		3	Pathogenic dermal fungi	Laboratory animal-Method for examination of Pathogenic dermal fungi GB/T14926.4-2026	only for M、R、H、GP、Rab、D、Mon、treeshrew、Pig、Gerbil	2026-07-28
		4	Streptobacillus moniliformis	Laboratory animal-Method for examination of Streptobacillus moniliformis GB/T14926.44-2001	only for M、R、H、GP	2026-07-28
		5	Bordetella bronchiseptica	Laboratory animal-Method for examination of Bordetella bronchiseptica GB/T14926.6-2001	only for R、H、GP、Gerbil	2026-07-28
				Detection of infectious atrophic rhinitis for swine NY/T 546-2015 6.2.2.1/6.3.1.1/6.4		2026-07-28
		6	Mycoplasma spp.	Laboratory animal-Method for examination of Mycoplasma spp. GB/T14926.8-2026	only for M、R、Pig、Gerbil	2026-07-28

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		7	Corynebacterium kutscheri	Laboratory animal-Method for examination of Corynebacterium kutscheri GB/T14926.9-2001	only for M、R、Gerbil	2026-07-28
		8	Tyzzer's organism	Laboratory animal-Method for examination of Tyzzer's organism GB/T14926.10-2008	only for M、R、H、GP、Rab、Gerbil	2026-07-28
		9	Citrobacter rodentium	Laboratory animal-Method for examination of Escherichia coli O115 a,C:K(B) GB/T14926.11-2001	only for M、Gerbil	2026-07-28
		10	Pasteurella pneumotropica	Laboratory animal-Method for examination of Pasteurella pneumotropica GB/T14926.12-2001	only for M、R、H、GP、Rab、Gerbil	2026-07-28
		11	Klebsiella pneumonia	Laboratory animal-Method for examination of Klebsiella pneumonia GB/T14926.13-2001	only for M、R、H、GP、Rab、Gerbil	2026-07-28
		12	Staphylococcus aureus	Laboratory animal-Method for examination of Staphylococcus aureus GB/T14926.14-2001	only for M、R、H、GP、Rab、treeshrew、Gerbil	2026-07-28
		13	Streptococcus pneumonia	Laboratory animal-Method for examination of Streptococcus pneumonia GB/T14926.15-2001	only for M、R、	2026-07-28

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					H、GP、Rab、treeshrew、Gerbil	
		14	β-hemolyticstreptococcus	Laboratory animal-Method for examination ofβ-hemolyticstreptococcus GB/T14926.16-2001	only for M、R、H、GP、Rab、treeshrew、Gerbil	2026-07-28
		15	Pseudomonas aeruginosa	Laboratory animal-Method for examination of Pseudomonas aeruginosa GB/T14926.17-2001	only for M、R、H、GP、Rab、treeshrew、Gerbil	2026-07-28
		16	Leptospira spp.	Laboratory animal-Method for examination of Leptospira spp. GB/T14926.46-2008	only for D、Pig	2026-07-28
		17	Shigella spp.	Laboratory animal-Method for examination of Shigella spp. GB/T14926.47-2008	only for Mon.	2026-07-28
		18	Mycobacterium tuberculosis	Laboratory animal-Method for examination of Mycobacterium tuberculosis GB/T14926.48-2001	only for Mon.、treeshrew	2026-07-28
		19	Campylobacter jejuni	Laboratory animal-Method for examination of Campylobacter jejuni GB/T14926.49-2001	only for D、Mon.、treeshrew	2026-07-28
		20	Detection of germ-free(Bacteria and fungi)	Laboratory animal-Method for examination of environment and faeces for GF animals GB/T14926.41-2001	only for M、R、	2026-07-28

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					H、GP、Rab、Gerbil、water、fodder、padding、faeces、environmental samples	
		21	Lymphocytic Choriomeningitis Virus	Laboratory animal-Method for examination of Lymphocytic Choriomeningitis Virus GB/T14926.18-2001	only for M、H、GP、Gerbil	2026-07-28
		22	Hantavirus	Laboratory animal-Method for examination of Hantavirus GB/T14926.19-2026	only for M、R、Gerbil、environment	2026-07-28
		23	Ectromelia Virus	Laboratory animal-Method for examination of Ectromelia Virus GB/T14926.20-2026 6.1~6.6,6.8	only for M、Environmental	2026-07-28
		24	Mouse Hepatitis Virus	Laboratory animal-Method for examination of Mouse Hepatitis Virus GB/T14926.22-2026	only for M、treeshrew、Gerbil、environment	2026-07-28

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		№	Item/ Parameter			
		25	Sendai Virus	Laboratory animal-Method for examination of Sendai Virus GB/T14926.23-2026	only for M、R、H、GP、Rab、Gerbil	2026-07-28
		26	Pneumonia Virus of Mice	Laboratory animal-Method for examination of Pneumonia Virus of Mice GB/T14926.24-2026	only for M、R、H、GP、Gerbil、environment	2026-07-28
		27	Reovirus type Ⅲ	Laboratory animal-Method for examination of Reovirus type Ⅲ GB/T14926.25-2026	only for M、R、H、GP、Gerbil、environment	2026-07-28
		28	Minute Virus of Mice	Laboratory animal-Method for examination of Minute Virus of Mice GB/T14926.28-2026	only for M、Gerbil、environment	2026-07-28
		29	Theiler's Mouse Encephalomyelitis Virus	Laboratory animal-Method for examination of Theiler's Mouse Encephalomyelitis Virus GB/T14926.26-2026	only for M, environment	2026-07-28
		30	Mouse Adenovirus	Laboratory animal-Method for examination of Mouse Adenovirus GB/T14926.27-2001	only for M	2026-07-28

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		31	Polyoma Virus	Laboratory animal-Method for examination of Polyoma Virus GB/T14926.29-2001	only for M	2026-07-28
		32	Rat Parvovirus (KRV and H-1 strain)	Laboratory animal-Method for examination of Rat Parvovirus(KRV and H-1 strain) GB/T14926.31-2001	only for R	2026-07-28
		33	Rat corona virus (RCV)/sialodacryoadenitis virus (SDAV)	Laboratory animal-Method for examination of rat corona virus (RCV)/sialodacryoadenitis virus (SDAV) GB/T14926.32-2001	only for R	2026-07-28
		34	Rabbit hemorrhagic disease Virus	Laboratory animal-Method for examination of Rabbit Hemorrhagic Disease Virus (RHDV) GB/T14926.21-2008	only for Rab	2026-07-28
		35	Rabbit Rotavirus	Laboratory animal-Method for examination of Rabbit Rotavirus (RRV) GB/T14926.30-2001	only for Rab	2026-07-28
		36	Rabies Virus	Laboratory animal-Method for examination of Rabies Virus GB/T14926.56-2008	only for D	2026-07-28
		37	Canine Parvovirus	Laboratory animal-Method for examination of Canine Parvovirus GB/T14926.57-2008	only for D	2026-07-28
		38	Canine Distemper Virus	Laboratory animal-Method for examination of Canine Distemper Virus (CDV) GB/T14926.59-2001	only for D	2026-07-28
		39	Infectious Canine Hepatitis Virus	Laboratory animal-Method for examination of Infectious Canine Hepatitis Virus GB/T14926.58-2008	only for D	2026-07-28
		40	Cercopithecine herpesvirus 1（B virus）	Laboratory animal-Method for examination of cercopithecine herpesvirus 1（B virus） GB/T14926.60-2001	only for Mon	2026-07-28
		41	Simian Retrovirus D	Laboratory animal-Method for examination of Simian Retrovirus D (SRV) GB/T14926.61-2001	only for Mon	2026-07-28
		42	Simian Immunodeficiency Virus	Laboratory animal-Method for examination of Simian Immunodeficiency Virus (SIV) GB/T14926.62-2026	only for Mon	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		43	Simian T Lymphotropic Virus type	Laboratory animal-Method for examination of Simian T Lymphotropic Virus type 1 (STLV-1) GB/T14926.63-2001	only for Mon	2026-07-28
		44	Simian Pox Virus	Laboratory animal-Method for examination of Simian Pox Virus (SPV) GB/T14926.64-2001	only for Mon	2026-07-28
		45	Detection virus from mice	Chinese Pharmacopoeia ,section 3(2025version) General principle 3303 Detection virus from mice	Biological products from Mice	2026-07-28
		46	Ectoparasites	Laboratory animal-Method for examination of Ectoparasites GB/T18448.1-2001	only for M、R、H、GP、Rab、D、Mon、treeshrew、Pig、Sheep、Gerbil	2026-07-28
		47	Toxoplasma gondii	Laboratory animal-Method for examination of Toxoplasma gondii GB/T18448.2-2008	only for M、R、H、GP、Rab、D、Mon、treeshrew、Pig、sheep、goat、Gerbil	2026-07-28
		48	Encephalitozoon cuniculi	Laboratory animal-Method for examination of Encephalitozoon cuniculi GB/T18448.3-2001	only for M、R、	2026-07-28

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		№	Item/ Parameter			
					GP、Rab、Gerbil	
		49	Pneumocystis sp.	Laboratory animal—Method for examination of *Pneumocystis* sp. GB/T14926.65-2026	only for Mouse、Rat、Rab、Guinea pig、Hamster	2026-07-28
		50	Eimeria spp.	Laboratory animal-Method for examination of Eimeria spp. GB/T18448.5-2001	only for H、Rab	2026-07-28
		51	Helminth	Laboratory animal-Method for examination of Helminth GB/T18448.6-2001	only for M、R、H、GP、Rab、D、Mon、treeshrew、Pig、Gerbil	2026-07-28
		52	Plasmodium spp.	Laboratory animal-Method for examination of Plasmodium spp. GB/T18448.7-2001	only for Mon	2026-07-28
		53	Dirofilaria immitis	Laboratory animal-Method for examination of Dirofilaria immitis GB/T18448.8-2001	only for D	2026-07-28
		54	Entamoeba histolytica	Laboratory animal-Method for examination of Entamoeba histolytica GB/T18448.9-2001	only for D、Mon	2026-07-28
		55	Flagellata and ciliata	Laboratory animal--Method for examination of Flagellata and ciliata GB/T18448.10-2001	only for M、R、	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					H、GP、Rab、D、Mon、treeshrew、Gerbil	
		56	Immunogene Monitoring in the Inbred Strain of Mice-Microcytotoxicity Test	Laboratory animal-immunological marker of inbred mice and rats GB/T14927.2-2008	only for M	2026-07-28
		57	Biochemical markers in experimental mice	Laboratory animal-Genetic monitoring: methods for biochemical markers of inbred mice and rats GB/T14927.1-2008	only for M	2026-07-28
		58	Biochemical markers in experimental rats	Laboratory animal-Genetic monitoring: methods for biochemical markers of inbred mice and rats GB/T14927.1-2008	only for R	2026-07-28
		59	Skin grafting of inbred mice and rats	Laboratory animal-immunological marker of inbred mice and rats GB/T14927.2-2008	only for M、R	2026-07-28
		60	Laboratory animal pathology	Medical Laboratory Animal Monitoring Manual: Laboratory Animal Pathology Monitoring Booklet（Ministry of Public Health,1992）,Summary of Laboratory Animal Pathology Monitoring(non-standard method)	only do gross anatomy,pathological slices and observation ;and only for M、R、H、GP、	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					Rab、D、Mon	
		61	Laboratory animal physiologycal biochemistry	National Guide to Clinical Laboratory Procedures(Forth Edition)blood, body fluid and chemistry analysis(2015)	only for M、R、H、GP、Rab、D、Mon	2026-07-28
		62	Validation of virus inactivation and clearance	The guidelines for the methods and validation of virus inactivation and clearance in blood products（2002）		2026-07-28
				General principles for review of virus safety assessment techniques for biological tissue extracts and eukaryotic expression products（2005）		2026-07-28
				Medical devices utilizing animal tissues and their derivatives Part 3:Validation of the elimination and/or inactivation of viruses and Transmissible Spongiform Encephalopathy(TSE) agents YY/T 0771.3-2009		2026-07-28
				Basic technical requirements of multi component biochemical drug injection (Trial Implementation,2008)		2026-07-28
				viral safety evaluation of biotechnology products derived from cell lines of human or animal origin ICH Q5A（R2）(Adopted on Novemeber 1,2023)		2026-07-28
		63	Salmonella pullorum	SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chicken GB/T17999.4-2008		2026-07-28
				Diagnostic techniques for fowl typhoid and pullorum disease NY/T 536-2017	only for chicken	2026-07-28
				SPF chicken-Microbiological surveillance-Part 8: Examination of Salmonella pullorum for SPF chicken GB/T17999.8-2008		2026-07-28
				SPF chicken-Microbiological surveillance-Part 9: Tube agglutination test for SPF chicken GB/T17999.9-2008		2026-07-28

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		№	Item/ Parameter			
		64	Avibacterium paragallinarum	SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chicken GB/T17999.4-2008		2026-07-28
				SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
				Diagnostic techniques for infectious coryza of chickens NY/T 538-2015		2026-07-28
		65	Pasteurella multocida	SPF chicken-Microbiological surveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008		2026-07-28
				Diagnostic techniques for fowl cholera (avian pasteurellosis) NY/T 563-2016		2026-07-28
				Laboratory animal-Method for examination of Pasteurella multocida GB/T14926.5-2001	only for H、GP、Rab、Gerbil	2026-07-28
				Detection of infectious atrophic rhinitis for swine NY/T 546-2015 6.2.2.2/6.3.2.1/6.4		2026-07-28
				NY/T 564-2002 Diagnostic techniques for swine pasteurellosis NY/T 564-2016 4.2/4.4		2026-07-28
		66	Mycoplasma gallisepticum	SPF chicken-Microbiological surveillance-Part 2：Hemagglutination inhibition test for SPF chicken GB/T17999.2-2008		2026-07-28
				SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chicken GB/T17999.4-2008		2026-07-28
				SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked GB/T17999.6-2008 3		2026-07-28
				Quarantine protocol for avain mycoplasmosis SN/T 1224-2012		2026-07-28
		67	Mycoplasma synoviae	SPF chicken-Microbiological surveillance-Part 2：Hemagglutination inhibition test for SPF chicken GB/T17999.2-2008		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				SPF chicken-Microbiological surveillance-Part 4: Serum plate agglutination test for SPF chicken GB/T17999.4-2008		2026-07-28
				SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
				Quarantine protocol for avain mycoplasmosis SN/T 1224-2012		2026-07-28
		68	Avian Influenza Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
		69	Newcastle Disease Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
		70	Infectious Bronchitis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
		71	Infectious Laryngotracheitis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
		72	Infectious Bursal Disease Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
		73	Lymphoid Leukosis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
		74	Reticuloendotheliosis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
		75	Marek′s Disease Virus	SPF chicken-Microbiological suiveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008		2026-07-28
		76	Chicken Infectious Anaemia Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
		77	Avian Reovirus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
		78	Avian Encephalomyelitis Virus	SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		79	Avian Adenovirus Group Ⅰ	SPF chicken-Microbiological suiveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008		2026-07-28
		80	Avian Adenovirus Group Ⅲ	SPF chicken-Microbiological surveillance-Part 2: Hemagglutination inhibition test for SPF chicken GB/T17999.2-2008		2026-07-28
				SPF chicken-Microbiological surveillance-Part 6: Enzyme-linked immunosorbent assay for SPF chicken GB/T17999.6-2008		2026-07-28
		81	Fowl Pox Virus	SPF chicken-Microbiological suiveillance-Part 5: Agar gel precipitation test for SPF chicken GB/T17999.5-2008		2026-07-28
		82	detection of avian virus	ChP. ChP.2025.Vol.III 3308and monographs		2026-07-28
		83	Classical swine fever virus, CSFV	Diagnostic techniques for classical swine fever(hog cholera) GB/T 16551-2020 7.3		2026-07-28
		84	Porcine reproductive and respiratory syndrome virus, PRRSV	Diagnostic techniques for porcine reproductive and respiratory syndrome GB/T 18090-2023 13		2026-07-28
		85	Pseudorabies virus, PrV	Diagnostic method for pseudorabies GB/T 18641-2018 7	only for Pig	2026-07-28
		86	Porcine parvovirus, PPV	Indirect ELISA for detection of antibodies against porcine parvovirus NY/T 2840-2015		2026-07-28
		87	Porcine circovirus type2, PCV2	Detecting procine cricovirus with polymerase chain reaction GB/T 21674-2008		2026-07-28
		88	Porcine transmissible gastroenteritia virus, TGEV	Quarantine protocol for transmissible gastroenteritis of swine SN/T 1446-2010 5.5		2026-07-28
		89	Swine vesicular disease virus,	Quarantine protocol for swine vesicular disease SN/T 2702-2010 5.7		2026-07-28

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		№	Item/ Parameter			
			SVDV			
		90	Actinobacillus pleuropeumoniae, APP	Diagnostic techniques for poecine contagious pleuropneumonia NY/T 537-2023 7-9		2026-07-28
		91	Streptococcus suis type 2	Procedure of plate and tube agglutination for Streptococcus suis type 2 GB/T 19915.1-2005		2026-07-28
				Methods for detection of Streptococcus suis type 2 GB/T 19915.2-2005		2026-07-28
				Method for detection Streptococcus suis type 2 by PCR GB/T 19915.3-2005		2026-07-28
				Method of the real-time PCR for the detection of Streptococcus suis type 2 GB/T 19915.7-2005		2026-07-28
		92	coccidium	Diagnostic techniques for animal coccidiosis GB/T 18647-2020 4.3.1	only for Pig	2026-07-28
		93	Vibrio cholerae	National Food Safety Standards Food microbiological testing Examination of Vibrio Parahaemolyticus GB 4789.7-2013 5	only for fish	2026-07-28
		94	Aeromonas hydrophila	Rules for quarantining bacterial diseases of fish Part3: Diagnostic method for bacterial enteritis SC/T 7201.3-2006		2026-07-28
		95	Streptococcus iniae	Method for examination of Streptococcus pneumonia GB/T 14926.15-2001	only for fish	2026-07-28
		96	Flavobacterium columnare	Rules for quarantining bacterial diseases of fish Part 2: Diagnostic method for gill-rot disease SC/T 7201.2-2006		2026-07-28
		97	Aeromonas veronii	Methods for detection of pathogenic aeromonas hydrophila GB/T 18652-2025	only for fish	2026-07-28
		98	Aeromonas jandaei	Methods for detection of pathogenic aeromonas hydrophila GB/T 18652-2025	only for fish	2026-07-28
		99	Saprolegnia spp.	National Food Safety Standards Food microbiological testting Enumeration of molds and yeasts GB 4789.15-2016	only for fish	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		100	Branchiomyces spp.	Protocol of quarantine for branchiomycosis of fish SN/T 2439-2010		2026-07-28
		101	Flavobacterium branchiophilum	Rules for quarantining bacterial diseases of fish Part 2: Diagnostic method for gill-rot disease SC/T 7201.2-2006		2026-07-28
		102	Flavobacterium psychrophilum	Rules for quarantining bacterial diseases of fish Part 2: Diagnostic method for gill-rot disease SC/T 7201.2-2006		2026-07-28
		103	Pseudomonas spp.	Rules for quarantining bacterial diseases of fish Part 4: Diagnostic method for Red-skin disease SC/T 7201.4-2006		2026-07-28
		104	Aeromonas sobri	Methods for detection of pathogenic aeromonas hydrophila GB/T 18652-2025		2026-07-28
		105	Streptococcus spp.	Laboratory animal-Method for examination of Streptococcus pneumonia and β hemolyic streptococcus GB/T 14926.15 and GB/T 14926.16	only for fish	2026-07-28
		106	Erysipelothrix rhusiopathiae	Diagnostic techniques for swine erysipelas NY/T 566-2019		2026-07-28
		107	Haemophilus parasuis	Diagnostic techniques for Glasser's disease GB/T 34750-2025		2026-07-28
		108	Coxiella burnetii	Quarantine protocol for Q fever SN/T 1087-2024 4.3	only for sheep and goat	2026-07-28
		109	Bacillus anthracis	Diagnostic techniques for animal anthrax NY/T 561-2015 6.6	only for sheep and goat	2026-07-28
		110	trichinella	Diagnostic techniques for trichinella spp. GB/T 18642-2021 5	only for Pig	2026-07-28
		111	cysticercus	Diagnostic techniques for cysticercosi s cellulosae GB/T 18644-2020 4	only for Pig	2026-07-28
		112	echinococcus	Diagnostic techniques for animal echinococcosis NY/T 1466-2018 3.3	only for sheep and goat	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		113	Highly pathogenic porcine reproductive and respiratory syndrome virus	A multiplex RT-PCR method to differentiate the highly pathogenic and classical porcine reproductive and respiratory syndrome virus GB/T 27517-2011		2026-07-28
		114	SV40（Simian vacuolating virus）	Pharmacopoeia of the People's Republic of China (2025 edition, part III) general rule 3304	Biological products derived from animal	2026-07-28
		115	Foot and mouth disease virus	Real-time RT-PCR for detection of foot and mouth disease virus GB/T 27528-2011	only for sheep and goat	2026-07-28
				Diagnostic techniques for foot and mouth disease GB/T 18935-2018 15	only for pig	2026-07-28
		116	Peste des petits ruminantsvirus	Diagnostic techniques for peste des petits ruminants GB/T 27982-2011 6.5		2026-07-28
		117	Sheep/ goat pox virus	Clinical diagnostic technology for sheep pox and goat pox NY/T 576-2015 4.3.5		2026-07-28
		118	Validation of sterilization by liquid sterilants	Sterilization of single — use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid sterilants YY0970-2013	materials of animal origin	2026-07-28
				Sterilization of health care products — Biological indicators — Part 1：General requirements Sterilization of health care products — Biological indicators — Part 1：General requirements GB/T 19973.1-2023		2026-07-28
				Sterilization of medical devices — Microbiological methods— Part 1：Determination of a population of microorganisms on products		2026-07-28
		119	Helicobacter pylori	《BERGEY'S MANUAL OF Systematic Bacteriology, Second Edition》Volume Two, The Proteobacteria, Part C The Alpha-,	only for M、Gerbil	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Beta-, Delta-, and Epsilonproteobacteria. Order I. Campylobacterales ord. nov., Family II. Helicobacteraceae fam. nov., Genus I. Helicobacter		
		120	Klebsiella oxytoca	《BERGEY'S MANUAL OF Systematic, Bacteriology Second Edition》Volume Two, The Proteobacteria, Part B The Gammaproteobacteria Order XIII. Enterobacteriales. Family I. Enterobacteriaceae, Genus XVI. Klebsiella SN/T 2552.9-2010	only for M、Gerbil	2026-07-28
		121	DNA barcode	Laboratory animal-Quality control of laboratory fish GB/T 39649-2020 4	Except for 4.2.3.3	2026-07-28
		122	microsatellite markers	Laboratory animal-Methods for microsatellite markers of laboratory mice & rats T/CALAS 21-2017	Except for 4.4.6	2026-07-28
		123	Helicobacter spp.	Laboratory animal- PCR Method for the detection of Helicobacter T/CALAS 24-2017	only for Mouse	2026-07-28
		124	Corynebacterium bovis	Laboratory animal-Method for examination of Corynebacterium bovis T/CALAS 20-2017	only for Mouse	2026-07-28
		125	Mycobacterium tuberculosis	Real-time PCR method for the detection of tuberculosis pathogenic organisms GB/T 27639-2011	only samples of Harmster, monkey	2026-07-28
		126	Burkholderia mallei	WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2023 Chapter 3.6.11- Glanders and Melioidosis 2.3.3 Real-time PCR assay	only for Equine	2026-07-28
		127	Salmonella abortus equi	Diagnostic techniques for equine abortus salmonellosis NY/T 570-2002		2026-07-28
				Defection methods of salmonella for animal and animal products NY/T 550-2002		2026-07-28
		128	Edwardsiella tarda	Detection methods for Edwardsiella from fish—Part 1:Edwardsiella tarda SC/T 7214.1-2011		2026-07-28
		129	Vibrio vulnificus	National food safety standards, microbiology detection, inspection of Vibrio vulnificus GB 4789.44-2020 5.3	only for Fish	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Laboratory animal—Quality control of laboratory fish GB/T 39649-2020 C.3	Only for Fish	2026-07-28
		130	Mycobacterium marinum	Laboratory animal-Quality control of laboratory fish GB/T 39649-2020 C.4		2026-07-28
		131	Mycoplasma hyopneumoniae	Diagnostic techniques for mycoplasmal pneumonia of swine NY/T 1186-2017 6.2/6.3.2		2026-07-28
		132	Serpul-Mahyodysenteriae	Quarantine protocol for swine dysentery SN/T 1207-2011	only for Pig	2026-07-28
		133	Brucella spp.	Diagnostic techniques for animal brucellosis GB/T 18646-2025 8.2/8.3/8.5/7.5	only for dog, pig , sheep or goat，equine	2026-07-28
				Laboratory animal—Method for examination of *Brucella* spp. GB/T 14926.45—2026 6.3,6.4,6.5,6.7,6.9,6.10	only for D、Pig、sheep and goat	2026-07-28
		134	Japanese encephalitis virus, JEV	Diagnostic techniques for Japanese encephalitis GB/T 18638-2021 10	only for Pig	2026-07-28
		135	murine norovirus	Laboratory animal-Methods for murine norovirus T/CALAS 22-2017 8		2026-07-28
		136	porcine parvovirus	Quarantine protocol for porcine parvovirus infection SN/T 1919-2016 7.6		2026-07-28
		137	African swine fever	Quarantine protocol for African swine fever SN/T1559—2024 10	only for Pig	2026-07-28
Packaging materials						
1	Packaging materials	1	Test for Skin Sensitization	National standards for pharmaceutical packaging materials Test for Skin Sensitization YBB00052003-2015		2026-07-28

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		2	Test for Acute Systemic Toxicity	National standards for pharmaceutical packaging materials Test for Acute Systemic Toxicity YBB00042003-2015		2026-07-28
		3	Test for Pyrogen	National standards for pharmaceutical packaging materials Test for Pyrogen YBB00022003-2015		2026-07-28
		4	Test for Hemolysis	National standards for pharmaceutical packaging materials Test for Hemolysis YBB00032003-2015		2026-07-28
		5	Test for eye Irritation	National standards for pharmaceutical packaging materials Test for eye Irritation YBB00062002-2015, YBB00072002-2015		2026-07-28
		6	Test for Cytotoxicity	National standards for pharmaceutical packaging materials Test for Cytotoxicity YBB00012003-2015		2026-07-28
		7	Test for Intracutaneous Irritation	National standards for pharmaceutical packaging materials Test for Intracutaneous Irritation YBB00062003-2015		2026-07-28
		8	Test for Primary Skin Irritation	National standards for pharmaceutical packaging materials Test for Primary Skin Irritation YBB00072003-2015		2026-07-28
Non-active medical device						
1	Pulmonary valve conduit	1	All items	Cardiovascular implants-Pulmonary valve conduit-Pulsatile flow test methods YY/T 1564-2017		2026-07-28
		2	All items	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020		2026-07-28
		3	appearance	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.1		2026-07-28
		4	specifications	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.2		2026-07-28
		5	durability	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.3		2026-07-28
		6	fluid dynamics	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	opening and closing state	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.5		2026-07-28
		8	Expanded inner diameter	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.6		2026-07-28
		9	Pipeline tensile strength	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.7		2026-07-28
		10	Bursting Strength	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.8		2026-07-28
		11	Tensile strength	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.9		2026-07-28
		12	permeability	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.10		2026-07-28
		13	thickness	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.11		2026-07-28
		14	Twist diameter	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.12		2026-07-28
		15	compliance	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.13		2026-07-28
		16	connection strength	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.1.14		2026-07-28
		17	pH	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.2.1		2026-07-28
		18	Heavy metal	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.2.2		2026-07-28
		19	residue	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.2.3		2026-07-28
		20	Other chemical properties	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.2.4		2026-07-28
		21	Sterility test	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.3.1		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Bacterial Endotoxins Test	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.3.2		2026-07-28
		23	Pyrogen Test	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.3.3		2026-07-28
		24	Calcification	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.3.4		2026-07-28
		25	Biological evaluation	Cardiovascular implants-Pulmonary valve conduit YY/T 1758-2020 5.3.5		2026-07-28
2	Medical devices for assisted reproductive technology	1	Partial items	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020	Except for ultrasonic detection	2026-07-28
		2	size	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.1.1		2026-07-28
		3	vacuum leak	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.1.2		2026-07-28
		4	flow	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.1.3		2026-07-28
		5	connection strength	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.1.4		2026-07-28
		6	appearance	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.1		2026-07-28
		7	cleanliness	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	rigidity	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.3		2026-07-28
		9	toughness	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.4		2026-07-28
		10	corrosion resistance	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.5		2026-07-28
		11	Puncture needle protective sleeve	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.2.7		2026-07-28
		12	appearance	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.3.1		2026-07-28
		13	positioning	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.3.2		2026-07-28
		14	pipe system	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.4		2026-07-28
		15	appearance	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.5.1		2026-07-28
		16	Egg protection	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.5.2		2026-07-28
		17	Inner cone joint	Medical devices for human assisted reproductive technology in vitroAssisted reproduction aspiration needles YY/T1698-2020 6.1.6		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Reducing substances	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.2		2026-07-28
		19	Metal Ion	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.3		2026-07-28
		20	pH	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.4		2026-07-28
		21	Evaporation residue	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.5		2026-07-28
		22	UV Absorbance	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.6		2026-07-28
		23	Ethylene oxide residue	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.2.7		2026-07-28
		24	Sterility test	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.3.1		2026-07-28
		25	Bacterial Endotoxins Test	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.3.2		2026-07-28
		26	Pyrogen Test	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.2		2026-07-28
		27	Hemolysis	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		28	Acute systemic toxicity	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.4		2026-07-28
		29	Cytotoxicity	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.5		2026-07-28
		30	Intradermal stimulation	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.6		2026-07-28
		31	Sensitization	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.7		2026-07-28
		32	Mouse embryo assay	Medical devices for human assisted reproductive technology in vitro-Assisted reproduction aspiration needles YY/T 1698-2020 6.4.8		2026-07-28
		33	Partial items	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020	Except for ultrasonic detection	2026-07-28
		34	size	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.1		2026-07-28
		35	Distance indicator signs	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.2		2026-07-28
		36	appearance	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.3		2026-07-28
		37	corrosion resistance	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.4		2026-07-28
		38	taper joint	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.6		2026-07-28
		39	flow	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.7		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		40	tightness	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.8		2026-07-28
		41	connection strength	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.1.9		2026-07-28
		42	Reducing substances	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.2		2026-07-28
		43	Metal Ion	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.3		2026-07-28
		44	pH	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.4		2026-07-28
		45	Evaporation residue	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.5		2026-07-28
		46	UV Absorbance	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.6		2026-07-28
		47	Ethylene oxide residue	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.2.7		2026-07-28
		48	Sterility test	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.3.1		2026-07-28
		49	Bacterial Endotoxins Test	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.3.2		2026-07-28
		50	Pyrogen Test	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.2		2026-07-28
		51	Cytotoxicity	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.3		2026-07-28
		52	Intradermal Test	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.4		2026-07-28
		53	Sensitization	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.5		2026-07-28
		54	Hemolysis	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.6		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		55	Acute systemic toxicity	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.7		2026-07-28
		56	Mouse embryo assay	Medical devices for human assisted reproductive technology in vitro-Embryo transfer catheters YY/T 1718-2020 6.4.8		2026-07-28
		57	Partial items	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022	Except for human sperm survival	2026-07-28
		58	size	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.1		2026-07-28
		59	appearance	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.2		2026-07-28
		60	bending resistance	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.3		2026-07-28
		61	Connection firmness	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.4		2026-07-28
		62	Inner cone joint	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.5		2026-07-28
		63	no leakage	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.6		2026-07-28
		64	Breaking force of conduit body	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.1.7		2026-07-28
		65	Reducing substances	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.2		2026-07-28
		66	Metal Ion	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.3		2026-07-28
		67	pH	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.4		2026-07-28
		68	Evaporation residue	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		69	UV Absorbance	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.6		2026-07-28
		70	Ethylene oxide residue	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.7		2026-07-28
		71	Other residues	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.2.8		2026-07-28
		72	Sterility test	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.3		2026-07-28
		73	Bacterial Endotoxins Test	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.4		2026-07-28
		74	Mouse embryo assay	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.5		2026-07-28
		75	Pyrogen Test	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.6.2		2026-07-28
		76	Cytotoxicity	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.6.3		2026-07-28
		77	Sensitization	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.6.4		2026-07-28
		78	vaginal irritation	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.6.5		2026-07-28
		79	Hemolysis	Medical devices for human assisted reproductive technology-Artificial insemination catheter YY/T 1769-2022 6.6.6		2026-07-28
		80	All items	Medical devices for human assisted reproductive technology-Determination of ammonium in human assisted reproductive media YY/T 1852-2022		2026-07-28
		81	Ion chromatography (Arbitration method)	Medical devices for human assisted reproductive technology-Determination of ammonium in human assisted reproductive media YY/T 1852-2022 4		2026-07-28
		82	Enzymatic method	Medical devices for human assisted reproductive technology-Determination of ammonium in human assisted reproductive		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				media YY/T 1852-2022 5		
		83	Partial items	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023	Except for human sperm survival	2026-07-28
		84	size	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.2.1		2026-07-28
		85	appearance	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.2.2		2026-07-28
		86	mechanical property	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.2.3		2026-07-28
		87	Other performance	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.2.4		2026-07-28
		88	Reducing substances	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.2		2026-07-28
		89	Metal Ion	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.3		2026-07-28
		90	pH	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.4		2026-07-28
		91	Evaporation residue	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		92	UV Absorbance	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.6		2026-07-28
		93	Ethylene oxide residue	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.7		2026-07-28
		94	Other residues	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.3.8		2026-07-28
		95	Sterility test	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.4		2026-07-28
		96	Bacterial Endotoxins Test	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.5		2026-07-28
		97	Biological evaluation	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.6		2026-07-28
		98	Safety evaluation of gametes and embryos	Medical devices for human assisted reproductive technology-General requirements of apparatus products YY/T 1914-2023 3.7		2026-07-28
3	Additive manufacturing	1	All items	Medical grade Ti-6Al-4V/Ti-6Al-4V ELIpowder used for additive manufacturing YY/T 1701-2020		2026-07-28
		2	Chemical composition	Medical grade Ti-6Al-4V/Ti-6Al-4V ELIpowder used for additive manufacturing YY/T 1701-2020 4.1		2026-07-28
		3	Appearance	Medical Ti-6Al-4V and Ti-6Al-4VELI powders for additive manufacturing YY/T 1701-2020 4.2.1		2026-07-28
		4	particle morphology	Medical Ti-6Al-4V and Ti-6Al-4VELI powders for additive manufacturing YY/T 1701-2020 4.2.2		2026-07-28
		5	Apparent density	Medical Ti-6Al-4V and Ti-6Al-4VELI powders for additive manufacturing YY/T 1701-2020 4.2.3		2026-07-28
		6	Tap density	Medical Ti-6Al-4V and Ti-6Al-4VELI powders for additive manufacturing YY/T 1701-2020 4.2.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Mobility	Medical Ti-6Al-4V and Ti-6Al-4VELI powders for additive manufacturing YY/T 1701-2020 4.2.5		2026-07-28
		8	All items	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022		2026-07-28
		9	Chemical composition	Medical pure tantalum powder for additive manufacturing YY/T1851-2022 4.1		2026-07-28
		10	Appearance	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.2.1		2026-07-28
		11	particle morphology	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.2.2		2026-07-28
		12	Apparent density	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.2.3		2026-07-28
		13	Tap density	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.2.4		2026-07-28
		14	Mobility	Medical pure tantalum powder for additive manufacturing YY/T 1851-2022 4.2.5		2026-07-28
		15	Hollow powder rate	Medical pure tantalum powder for additive manufacturing YY/T1851-2022 4.2.6		2026-07-28
		16	Partial items	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T 1910-2023	Except for X-ray diffraction beta-tricalcium phosphate content, calcium phosphorus atomic ratio, specific	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					surface area	
		17	Appearance	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T 1910-2023 4.1		2026-07-28
		18	infrared absorption spectrum	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T 1910-2023 4.5		2026-07-28
		19	Particle size and distribution	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T 1910-2023 4.6		2026-07-28
		20	Powder morphology	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T 1910-2023 4.7		2026-07-28
		21	pH	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T1910-2023 4.8		2026-07-28
		22	Content of trace elements and total amount of heavy metals	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T1910-2023 4.9		2026-07-28
		23	water content	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YY/T1910-2023 4.10		2026-07-28
		24	Apparent density	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YYT 1910-2023 4.12		2026-07-28
		25	Tap density	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YYT 1910-2023 4.13		2026-07-28
		26	Mobility	Medical-grade beta-tricalcium phosphate powder for additive manufacturing YYT 1910-2023 4.14		2026-07-28
4	Preclinical animal study of medical devices	1	Partial items	Preclinical animal study of medical devices-Part 2：Model of skin defect in induced diabetic rats YY/T 1754.2-2020	Except for histopathology	2026-07-28
5	Implants for surgery	1	All items	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	appearance	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.1		2026-07-28
		3	thickness	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.2		2026-07-28
		4	tensile strength	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.3		2026-07-28
		5	tensile elongation	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.4		2026-07-28
		6	seam strength	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.5		2026-07-28
		7	Bursting Strength	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.6		2026-07-28
		8	tear strength	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.7		2026-07-28
		9	aperture	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.8		2026-07-28
		10	Connecting Force	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.1.9		2026-07-28
		11	pH	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.2		2026-07-28
		12	Total heavy metals and trace elements	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.3		2026-07-28
		13	Reducing substances	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.4		2026-07-28
		14	UV Absorbance	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.5		2026-07-28
		15	evaporation residue	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.6		2026-07-28
		16	infrared spectrum	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.7		2026-07-28

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		№	Item/ Parameter			
		17	Supplementary inspection items	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.8		2026-07-28
		18	Ethylene oxide residue	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.2.9		2026-07-28
		19	Sterility test	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.3.2		2026-07-28
		20	Bacterial endotoxins test	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.3.3		2026-07-28
		21	Biological evaluation	Implants for surgery -Synthetic non-absorbable patch-Hernia repair patch YY/T 1814-2022 4.3.4		2026-07-28
		22	Partial items	Implants for surgery -Synthestic non-absorbable patch-Dura patch YY/T 1816-2022	Except for surface structure	2026-07-28
		23	appearance	Implants for surgery -Synthestic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.1		2026-07-28
		24	thickness	Implants for surgery -Synthestic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.2		2026-07-28
		25	tensile strength	Implants for surgery -Synthestic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.4		2026-07-28
		26	seam strength	Implants for surgery -Synthestic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.5		2026-07-28
		27	elongation at break	Implants for surgery -Synthestic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.6		2026-07-28
		28	Anti permeability performance	Implants for surgery -Synthestic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.7		2026-07-28
		29	taper joint	Implants for surgery -Synthestic non-absorbable patch-Dura patch YY/T 1816-2022 4.1.8		2026-07-28
		30	pH	Implants for surgery -Synthestic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.2		2026-07-28

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		№	Item/ Parameter			
		31	Total heavy metals and trace elements	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.3		2026-07-28
		32	Reducing substances	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.4		2026-07-28
		33	UV Absorbance	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.5		2026-07-28
		34	evaporation residue	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.6		2026-07-28
		35	infrared spectrum	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.7		2026-07-28
		36	Supplementary inspection items	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.8		2026-07-28
		37	Ethylene oxide residue	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.2.9		2026-07-28
		38	Bacterial Endotoxins Test	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.3.2		2026-07-28
		39	Sterility test	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.3.3		2026-07-28
		40	Biological evaluation	Implants for surgery -Synthetic non-absorbable patch-Dura patch YY/T 1816-2022 4.3.4		2026-07-28
		41	All items	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021		2026-07-28
		42	appearance	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.1		2026-07-28
		43	size	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.2		2026-07-28
		44	structural feature	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.3		2026-07-28
		45	tensile strength	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		46	seam strength	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.5		2026-07-28
		47	elongation at break	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.6		2026-07-28
		48	Bursting Strength	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.7		2026-07-28
		49	tear strength	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.8		2026-07-28
		50	Anti permeability performance	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.2.9		2026-07-28
		51	pH	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.3.1		2026-07-28
		52	Total heavy metals and trace elements	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.3.2		2026-07-28
		53	Ethylene oxide residue	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.3.3		2026-07-28
		54	Main components	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.3.4		2026-07-28
		55	Other Items	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.3.5		2026-07-28
		56	Sterility test	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.4.1		2026-07-28
		57	Bacterial Endotoxins Test	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.4.2		2026-07-28
		58	Biological evaluation	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.4.3		2026-07-28
		59	Immunogenicity evaluation	Implants for surgery -General requirements for animal-derived patch products YY/T 1788-2021 4.4.4		2026-07-28
6	Allogeneic bone grafts	1	All items	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009	Use only when	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					quoted or requested by the customer	
		2	Specification	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.1	Only used when cited or requested by a customer	2026-07-28
		3	Appearance	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.2	Only used when cited or requested by a customer	2026-07-28
		4	pH value	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.3	Only used when cited or requested by a customer	2026-07-28
		5	Water content	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.4	Only used when cited or requested by a customer	2026-07-28
		6	Cytotoxicity	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.5.1	Only used when cited	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					or requested by a customer	
		7	Sensitization	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.5.2	Only used when cited or requested by a customer	2026-07-28
		8	Genotoxicity test	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.5.3	Only used when cited or requested by a customer	2026-07-28
		9	Implant test	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.5.4	Only used when cited or requested by a customer	2026-07-28
		10	Test for the introduction of ectopic osteogenesis	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.5.5	Only used when cited or requested by a customer	2026-07-28
		11	Sterility test	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.6	Only used when cited	2026-07-28

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		№	Item/ Parameter			
					or requested by a customer	
		12	Degree of Demineralization	Allogeneic bone grafts Part3：Demineralized allogeneic bone grafts YY/T 0513.3-2009 6.7	Only used when cited or requested by a customer	2026-07-28
7	Heart valve substitutes implanted by transcatheter techniques	1	Partial items	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016	Except for visibility and MRI safety	2026-07-28
		2	Packaging, labeling and sterilization	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 6.2.4		2026-07-28
		3	Hydrodynamic performance assessment	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.3		2026-07-28
		4	Structural performance assessment	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.4		2026-07-28
		5	Device migration resistance	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.1		2026-07-28
		6	Implant foreshortening	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Crush resistance	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.4		2026-07-28
		8	Recoil	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.5		2026-07-28
		9	Size	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.6		2026-07-28
		10	Radial resistive force	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.7		2026-07-28
		11	Chronic outward force	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.5.8		2026-07-28
		12	Delivery system design evaluation requirements	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.6		2026-07-28
		13	Testing related to specific designs	Cardiovascular implants—Cardiac valve prostheses—Part 3:Heart valve substitutes implanted by transcatheter techniques YY/T 1449.3-2016 7.2.7		2026-07-28
8	Vascular stents	1	All items	Standard test methods for in vitro pulsatile durability testing of vascular stents YY/T 0808-2010		2026-07-28
9	Stainless steel needle tubing for the manufacture of medical devices	1	All items	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Size	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 4	Use only when quoted or requested by the customer	2026-07-28
		3	Specification annotation	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 5	Use only when quoted or requested by the customer	2026-07-28
		4	surface	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 6	Use only when quoted or requested by the customer	2026-07-28
		5	cleanliness	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 7	Use only when quoted or requested by the customer	2026-07-28
		6	pH value	Stainless steel needle tubing for the manufacture of medical devices GB/T18457-2015 8	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	rigidity	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 9	Use only when quoted or requested by the customer	2026-07-28
		8	toughness	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 10	Use only when quoted or requested by the customer	2026-07-28
		9	corrosion resistance	Stainless steel needle tubing for the manufacture of medical devices GB/T 18457-2015 11	Use only when quoted or requested by the customer	2026-07-28
10	Stainless Steel Needles for Prefilled Syringes	1	All items	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		2	appearance	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	rigidity	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		4	toughness	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		5	corrosion resistance	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		6	Foreign objects on the inner surface of the needle tube	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		7	Needle hole patency	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Puncture force of needle tip	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		9	Connection force between needle and needle seat	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		10	Pullout force of needle protective cap	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		11	pH value	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		12	Cadmium ion	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		13	Heavy metals	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		14	Cytotoxicity	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		15	Sensitization	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		16	Irritation	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
		17	Acute systemic toxicity	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28

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		18	Hemolysis test	Stainless Steel Needles for Prefilled Syringes YBB 00092004-2015	Use only when quoted or requested by the customer	2026-07-28
11	medical devices	1	Pyrogen Test	ChP 2025 年版四部 通则 (1142)		2026-07-28
		2	Bacterial Endotoxins Test	ChP 2025 年版四部 通则 (1143)		2026-07-28
		3	Sterility Test Technology	ChP 2025 年版四部 通则 (1101)		2026-07-28
		4	Protein content determination method	ChP 2025 年版四部 通则（0731）		2026-07-28
		5	molecular-exclusion chromatography method	ChP 2025 年版四部 通则（0514）	"Except for Size Exclusion Chromatography- Static Light Scattering (SEC-SLS) Method"	2026-07-28
		6	transformation temperature	Standard test method for transformation temperature of nickel-Tianium alloys by thermal analysis YY/T 0641-2008		2026-07-28
		7	Vickers hardness test	Metallic materials--Vickers hardness test—Part1：Test method GB/T 4340.1-2009		2026-07-28
		8	corrosion resistance	Medical instruments of stain less steel-Test methods of corrosion resistance YY/T 0149-2006		2026-07-28

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		9	corrosion resistance	Standard test method for conducting cyclic potentiodynamic polarization measurements to determine the corrosion susceptibility of small Implant devices YY/T 0695-2008		2026-07-28
		10	MS	ChP 2025 年版四部 通则 (0431)		2026-07-28
		11	In vitro mammalian chromosome aberration test	Test for genotoxicity of medical devices—Part 2:In vitro mammalian chromosome aberration test YY/T 0870.2-2019		2026-07-28
		12	TK gene mutation test	Test for genotoxicity of medical devices—Part 3:TK gene mutation test using mouse lymphoma cells YY/T 0870.3-2019		2026-07-28
		13	pH measurement method	ChP 2025 年版四部 通则（0631）		2026-07-28
		14	Heavy metal inspection method	ChP 2025 年版四部 通则（0821）		2026-07-28
		15	Infrared spectrophotometry method	ChP 2025 年版四部 通则（0402）		2026-07-28
		16	ultraviolet-visible spectrophotometry method	ChP 2025 年版四部 通则（0401）		2026-07-28
		17	Clarity	ChP 2025 年版四部 通则（0902）		2026-07-28
		18	Color	ChP 2025 年版四部 通则（0901）		2026-07-28
		19	Residue on Ignition	ChP 2025 年版四部 通则（0841）		2026-07-28
		20	Residual solvents	ChP 2025 年版四部 通则（0861）		2026-07-28
		21	Atomic absorption spectrophotometry method	ChP 2025 年版四部 通则（0406）		2026-07-28

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		№	Item/ Parameter			
		22	High Performance Liquid Chromatography	ChP 2025 年版四部 通则（0512）	不做多维液相色谱法	2026-07-28
		23	Gas Chromatography	ChP 2025 年版四部 通则（0521）		2026-07-28
		24	Microbial limits test	ChP 2025 年版四部 通则 (1105)，(1106)		2026-07-28
		25	X-ray fluorescence spectroscopy	ChP 2025 VOL IV （0461）		2026-07-28
		26	characterizaiton of hydrogels	Tissue engineering medical products-Standard guide for characterizaiton of hydrogels YY/T 1435-2016		2026-07-28
		27	T lymphocyte transformation test in vitro	T lymphocyte transformation test in vitro YY/T 1465.1—2016		2026-07-28
		28	anti-calcification evaluation	Anti-calcification evaluation of animal derived cardiovascular implants—Test for rat subcutaneous implantation YY/T 1859-2022		2026-07-28
		29	In vivo evaluation of osteoinductive potential	Allogeneic grafts -In vivo evaluation of osteoinductive potential for materials containing demineralized bon YY/T 1680-2020		2026-07-28
		30	Determination of silver contents in biological samples	Nanotechnology—Determination of silver contents in biological samples — Inductively coupled plasma mass spectrometry GB/T 38261-2019		2026-07-28
		31	Method to measure cell miagration in porous materials	Tissue engineering medical products-Bioactive ceramics-Method to measure cell miagration in porous materials YY/T 1744-2020		2026-07-28
		32	pyrogen	Pyrogen test for medical devices— Monocyte-activation test Human whole bloodELISA method YY/T 1500-2016		2026-07-28
12	Cardiovascular implants and	1	All Parameters	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches			0500-2021		
		2	Residual chemical substances	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.5.1		2026-07-28
		3	Biological evaluation	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.5.2		2026-07-28
		4	Permeaiblity	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.1		2026-07-28
		5	Mechanical strength	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.2		2026-07-28
		6	Length	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.3		2026-07-28
		7	Relaxed internal diameter	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.4		2026-07-28
		8	Pressurized internal diameter	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.5		2026-07-28
		9	Wall thickness	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.6		2026-07-28
		10	Suture retention strength	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.7		2026-07-28
		11	Kink	Cardiovascular implants and extracorporeal systems-vascular		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			diameter/radium	prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.8		
		12	Dynamic radial compliance	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.2.9		2026-07-28
		13	Permeaiblity	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.3.1		2026-07-28
		14	Mechanical strength	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.3.2		2026-07-28
		15	Length and width	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.3.3		2026-07-28
		16	Wall thickness	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.3.4		2026-07-28
		17	Suture retention strength	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 8.7.3.5		2026-07-28
		18	Preclinical in vivo evaluation of vascular prostheses	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 9		2026-07-28
		19	Sterility	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 12		2026-07-28
		20	Packaging and Labeling	Cardiovascular implants and extracorporeal systems-vascular prostheses-tubular vascular grafts and vascular patches YY/T 0500-2021 13		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
13	Mammary implants	1	All items	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021		2026-07-28
		2	cytotoxicity	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 6.2		2026-07-28
		3	residual low molecular weight oligomers	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 6.3		2026-07-28
		4	trace elements	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 6.4		2026-07-28
		5	Mechanical test	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 7.2.2		2026-07-28
		6	physical evaluation	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 7.2.3		2026-07-28
		7	sterility	Non-active surgical implants-Particular requirements of mammary implants YY/T 0647-2021 9		2026-07-28
14	Hip joint prostheses	1	All items	Joint replacement implants-Hip joint prostheses YY 0118-2016		2026-07-28
		2	Metal Material	Joint replacement implants-Hip joint prostheses YY 0118-2016 7.2		2026-07-28
		3	Ultra-High Molecular Weight Polyethylene (UHMWPE) Material	Joint replacement implants-Hip joint prostheses YY 0118-2016 7.3		2026-07-28
		4	Ceramic Materials	Joint replacement implants-Hip joint prostheses YY 0118-2016 7.4		2026-07-28
		5	Coating Materials	Joint replacement implants-Hip joint prostheses YY 0118-2016 7.5		2026-07-28
		6	Appearance	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Surface defects	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.3		2026-07-28
		8	Surface roughness	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.4		2026-07-28
		9	Dimensions and tolerances of important parts	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.5		2026-07-28
		10	Static mechanical properties	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.6		2026-07-28
		11	Dynamic mechanics	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.7		2026-07-28
		12	Min and Max Angles	Joint replacement implants-Hip joint prostheses YY 0118-2016 8.8		2026-07-28
		13	Sterility	Joint replacement implants-Hip joint prostheses YY 0118-2016 10		2026-07-28
15	Knee joint prostheses	1	All items	Joint replacement implants- Knee joint prostheses YY 0502-2016		2026-07-28
		2	Metal Material	Joint replacement implants- Knee joint prostheses YY 0502-2016 7.2		2026-07-28
		3	Ultra-High Molecular Weight Polyethylene (UHMWPE) Material	Joint replacement implants- Knee joint prostheses YY 0502-2016 7.3		2026-07-28
		4	Ceramic Materials	Joint replacement implants- Knee joint prostheses YY 0502-2016 7.4		2026-07-28
		5	Coating Materials	Joint replacement implants- Knee joint prostheses YY 0502-2016 7.5		2026-07-28
		6	appearance	Joint replacement implants- Knee joint prostheses YY 0502-2016 8.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Surface defects	Joint replacement implants- Knee joint prostheses YY 0502-2016 8.3		2026-07-28
		8	Surface roughness	Joint replacement implants- Knee joint prostheses YY 0502-2016 8.4		2026-07-28
		9	Dimensions and tolerances of important parts	Joint replacement implants- Knee joint prostheses YY 0502-2016 8.5		2026-07-28
		10	dynamic mechanics	Joint replacement implants- Knee joint prostheses YY 0502-2016 8.6		2026-07-28
		11	Relative angular motion range	Joint replacement implants-Knee joint prostheses YY 0502-2016 8.7		2026-07-28
		12	Sterility	Joint replacement implants-Knee joint prostheses YY 0502-2016 10		2026-07-28
16	Metallic bone screws	1	All items	Implants for osteosynthesis-Metallic bone screws YY 0018－2016		2026-07-28
		2	Material	Implants for osteosynthesis-Metallic bone screws YY 0018-2016 5.1		2026-07-28
		3	Maximum torque and breaking torque angle	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.2.1		2026-07-28
		4	hardness	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.2.2		2026-07-28
		5	Axial extraction force	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.2.3		2026-07-28
		6	Screw in torque and screw out torque	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.2.4		2026-07-28
		7	Self tapping performance	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.2.5		2026-07-28
		8	corrosion resistance	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Surface defects	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.4.1		2026-07-28
		10	Surface roughness	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.4.2		2026-07-28
		11	appearance	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.4.3		2026-07-28
		12	Surface Treatment	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.4.4		2026-07-28
		13	size	Implants for osteosynthesis--Metallic bone screws YY 0018-2016 5.5		2026-07-28
17	Metallic medullary pins	1	All items	Implants for surgery-Intramedullary nailing systems - Part 2: Medullary pins YY/T 0019.2-2011		2026-07-28
		2	Material	Implants for surgery-Intramedullary nailing systems - Part 2: Medullary pins YY/T 0019.2-2011 3		2026-07-28
		3	appearance	Implants for surgery-Intramedullary nailing systems - Part 2: Medullary pins YY/T 0019.2-2011 5		2026-07-28
		4	size	Implants for surgery-Intramedullary nailing systems - Part 2: Medullary pins YY/T 0019.2-2011 6		2026-07-28
18	Metallic spinal screws	1	All items	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2:Metallic spinal screws YY/T 0119.2-2014		2026-07-28
		2	Geometric characteristics	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2:Metallic spinal screws YY/T 0119.2-2014 5.1		2026-07-28
		3	Rotational connection	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2:Metallic spinal screws YY/T 0119.2-2014 5.2		2026-07-28
		4	Torsion property	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2:Metallic spinal screws YY/T 0119.2-2014 5.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Rotational torque	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2:Metallic spinal screws YY/T 0119.2-2014 5.4		2026-07-28
		6	Axial extraction force	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2:Metallic spinal screws YY/T 0119.2-2014 5.5		2026-07-28
		7	Flexural properties	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part2:Metallic spinal screws YY/T 0119.2-2014 5.6		2026-07-28
19	Metallic spinal rods	1	All items	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part4:Metallic spinal rods YY/T 0119.4-2014		2026-07-28
		2	Geometric characteristics	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part4:Metallic spinal rods YY/T 0119.4-2014 5.1		2026-07-28
		3	Static and fatigue tests	Spinal implants-Components used in the surgical fixation of the spinal skeletal system-Part4:Metallic spinal rods YY/T 0119.4-2014 5.2		2026-07-28
20	Metal bone pins	1	All items	Implants for surgery—Metallic skeletal pins and wires-Part 1:General requirements YY/T 0345.1-2020		2026-07-28
		2	Mechanical properties	Implants for surgery—Metallic skeletal pins and wires-Part 1:General requirements YY/T 0345.1-2020 4		2026-07-28
		3	Manufacturing method	Implants for surgery—Metallic skeletal pins and wires-Part 1:General requirements YY/T 0345.1-2020 5		2026-07-28
		4	Surface quality	Implants for surgery—Metallic skeletal pins and wires-Part 1:General requirements YY/T 0345.1-2020 6		2026-07-28
		5	Sterilization	Implants for surgery—Metallic skeletal pins and wires-Part 1:General requirements YY/T 0345.1-2020 7		2026-07-28
		6	All items	Implants for surgery-Skeletal pins and wires-Part2:Steinmann skeletal pins-Dimensions YY/T 0345.2-2014		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	size	Implant for surgery-Skeletal pins and wires-Part2:Steinmann skeletal pins-Dimensions YY/T 0345.2-2014 2		2026-07-28
		8	end	Implant for surgery-Skeletal pins and wires-Part2:Steinmann skeletal pins-Dimensions YY/T 0345.2-2014 3		2026-07-28
		9	All items	Implants for surgery-Skeletal pins and wires-Part 3:kirschner skeletal wires YY/T 0345.3-2014		2026-07-28
		10	size	Implants for surgery-Skeletal pins and wires-Part 3:kirschner skeletal wires YY/T 0345.3-2014 3		2026-07-28
		11	end	Implants for surgery-Skeletal pins and wires-Part 3:kirschner skeletal wires YY/T 0345.3-2014 4		2026-07-28
21	Metallic bone plates	1	All items	Implants for osteosynthesis- Metallic bone plates YY 0017-2016		2026-07-28
		2	Material	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.1		2026-07-28
		3	Hardness	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.2.1		2026-07-28
		4	Bending strength and equivalent bending stiffness	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.2.2		2026-07-28
		5	Fatigue performance	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.2.3		2026-07-28
		6	the corrosion susceptibility	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.3		2026-07-28
		7	Surface defects	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.4.1		2026-07-28
		8	Surface roughness	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.4.2		2026-07-28
		9	Appearance	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.4.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Surface Treatment	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.4.4		2026-07-28
		11	Geometric characteristics	Implants for osteosynthesis- Metallic bone plates YY 0017-2016 4.5		2026-07-28
22	Metallic fixation screw for femur neck	1	All items	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022		2026-07-28
		2	Maximum torque and torsion angle at break	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.1		2026-07-28
		3	hardness	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.2		2026-07-28
		4	Axial insertion force	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.3		2026-07-28
		5	Axial pull-out force	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.4		2026-07-28
		6	Screw-in torque and spin-out torque	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.5		2026-07-28
		7	Self-tapping performance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.6		2026-07-28
		8	Static bending performance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.7		2026-07-28
		9	Fatigue bending performance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.2.8		2026-07-28
		10	Corrosion resistance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.3		2026-07-28
		11	Surface roughness	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.4.2		2026-07-28
		12	appearance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.4.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Anodized surface treatment（cytotoxicity）	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.4.4		2026-07-28
		14	size	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.5		2026-07-28
		15	Fit performance	Implants for osteosynthesis-Metallic fixation screw for femur neck YY/T 0346-2022 4.6		2026-07-28
23	Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings	1	All items	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005		2026-07-28
		2	Raw Material and Forged Material Chemical Composition	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005 3.1.2		2026-07-28
		3	Mechanical	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005 3.4		2026-07-28
		4	surface quality	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005 3.5		2026-07-28
		5	Internal Quality	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005 3.6		2026-07-28
		6	Outline dimensions of forgings	Implants for surgery-Forgings, castings for bone joint prostheses-Ti6Al4V titanium alloy forgings YY 0117.1-2005 3.7		2026-07-28
24	Forgings,castings for bone joint prostheses-ZTi6Al4V alloy castings	1	All items	Implants for surgery-Forgings,castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005		2026-07-28
		2	Alloy Chemical Composition	Implants for surgery-Forgings,castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.1.2		2026-07-28
		3	Casting Chemical Composition	Implants for surgery-Forgings,castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.2		2026-07-28
		4	Mechanical	Implants for surgery-Forgings,castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	surface quality	Implants for surgery-Forgings,castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.6		2026-07-28
		6	Internal Quality	Implants for surgery-Forgings,castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.7		2026-07-28
		7	Outline dimensions of forgings	Implants for surgery-Forgings,castings for bone joint prostheses-ZTi6Al4V alloy castings YY 0117.2-2005 3.8		2026-07-28
25	Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings	1	All items	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005		2026-07-28
		2	Alloy and Casting Chemical Composition	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005 3.1		2026-07-28
		3	Mechanical	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005 3.4		2026-07-28
		4	Surface quality	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005 3.5		2026-07-28
		5	Internal Quality	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005 3.6		2026-07-28
		6	Outline dimensions of forgings	Implants for surgery-Forgings, castings for bone joint prostheses-Cobalt chromium molybdenum alloy castings YY 0117.3-2005 3.7		2026-07-28
26	Implants for surgery Fundamental principles	1	All items	Implants for surgery Fundamental principles YY/T 0340-2009		2026-07-28
27	Non-active surgical implants-	1	All items	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Osteosynthesis and spinal implants	2	hardness	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.2		2026-07-28
		3	Static and/or dynamic mechanical properties	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.3		2026-07-28
		4	Corrosion resistance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.4		2026-07-28
		5	Surface roughness	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.5.2		2026-07-28
		6	appearance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.5.3		2026-07-28
		7	Important part size	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.6		2026-07-28
		8	Fit performance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.7		2026-07-28
		9	sterility	Non-active surgical implants-Osteosynthesis and spinal implants-Part 1: Particular requirements for osteosynthesis implants YY 0341.1-2020 4.8		2026-07-28
		10	All items	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020		2026-07-28
		11	hardness	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Static and/or dynamic mechanical properties	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.3		2026-07-28
		13	Corrosion resistance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.4		2026-07-28
		14	Surface roughness	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.5.2		2026-07-28
		15	appearance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.5.3		2026-07-28
		16	Important part size	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.6		2026-07-28
		17	hydroxyapatite coating	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.7.1		2026-07-28
		18	Metal spine implant Thermal spraying pure titanium coating	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.7.2		2026-07-28
		19	Fit performance	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.8		2026-07-28
		20	sterility	Non-active surgical implants-Osteosynthesis and spinal implants-Part 2: Particular requirements for spinal implants YY 0341.2-2020 4.9		2026-07-28
28	Hygienic standard for	1	All items	Hygienic standard for yuangong intrauterine device of specially designed inserter YY/T 0470-2004		2026-07-28

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		№	Item/ Parameter			
	yuangong intrauterine device of specially designed inserter	2	Usage performance	Hygienic standard for yuangong intrauterine device of specially designed inserter YY/T 0470-2004 4.1		2026-07-28
		3	Ethylene Oxide Residue	Hygienic standard for yuangong intrauterine device of specially designed inserter YY/T0470-2004 4.2.2		2026-07-28
		4	appearance	Hygienic standard for yuangong intrauterine device of specially designed inserter YY/T 0470-2004 4.3		2026-07-28
29	Uterine cavity form intra-uterine devices	1	All items	Uterine cavity form intra-uterine devices GB 11234-2006	Use only when quoted or requested by the customer	2026-07-28
		2	Material	Uterine cavity form intra-uterine devices GB 11234-2006 3.1	Use only when quoted or requested by the customer	2026-07-28
		3	appearance	Uterine cavity form intra-uterine devices GB 11234-2006 4.1	Use only when quoted or requested by the customer	2026-07-28
		4	size	Uterine cavity form intra-uterine devices GB 11234-2006 4.2	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	performance	Uterine cavity form intra-uterine devices GB 11234-2006 4.3	Use only when quoted or requested by the customer	2026-07-28
		6	Sterility	Uterine cavity form intra-uterine devices GB 11234-2006 4.4	Use only when quoted or requested by the customer	2026-07-28
		7	Ethylene Oxide Residue	Uterine cavity form intra-uterine devices GB 11234-2006 4.5	Use only when quoted or requested by the customer	2026-07-28
		8	Biological evaluation	Uterine cavity form intra-uterine devices GB 11234-2006 4.6	Use only when quoted or requested by the customer	2026-07-28
30	OCu intra-uterine devices	1	All items	OCu intra-uterine devices GB 3156-2006	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Material	OCu intra-uterine devices GB 3156-2006 3.1	Use only when quoted or requested by the customer	2026-07-28
		3	package	OCu intra-uterine devices GB 3156-2006 4.1	Use only when quoted or requested by the customer	2026-07-28
		4	appearance	OCu intra-uterine devices GB 3156-2006 4.2	Use only when quoted or requested by the customer	2026-07-28
		5	performance	OCu intra-uterine devices GB 3156-2006 4.3	Use only when quoted or requested by the customer	2026-07-28
		6	Sterility	OCu intra-uterine devices GB 3156-2006 4.4	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Ethylene Oxide Residue	OCu intra-uterine devices GB 3156-2006 4.5	Use only when quoted or requested by the customer	2026-07-28
		8	Biological evaluation	OCu intra-uterine devices GB 3156-2006 4.6	Use only when quoted or requested by the customer	2026-07-28
31	VCu intra-uterine devices	1	All items	VCu intra-uterine devices GB 11235-2006	Use only when quoted or requested by the customer	2026-07-28
		2	Material	VCu intra-uterine devices GB 11235-2006 3.1		2026-07-28
		3	appearance	VCu intra-uterine devices GB 11235-2006 4.1		2026-07-28
		4	package	VCu intra-uterine devices GB 11235-2006 4.2		2026-07-28
		5	central filaments corrosion preventive	VCu intra-uterine devices GB 11235-2006 4.3		2026-07-28
		6	central filaments roughness	VCu intra-uterine devices GB 11235-2006 4.4		2026-07-28
		7	copper wire surface area	VCu intra-uterine devices GB 11235-2006 4.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Tail tensile resistance	VCu intra-uterine devices GB 11235-2006 4.6		2026-07-28
		9	Length and appearance	VCu intra-uterine devices GB 11235-2006 4.7		2026-07-28
		10	Center wire hardness	VCu intra-uterine devices GB 11235-2006 4.8		2026-07-28
		11	elasticity	VCu intra-uterine devices GB 11235-2006 4.9		2026-07-28
		12	resistance to displacement	VCu intra-uterine devices GB 11235-2006 4.10		2026-07-28
		13	Sterility	VCu intra-uterine devices GB 11235-2006 4.11		2026-07-28
		14	Ethylene Oxide Residue	VCu intra-uterine devices GB 11235-2006 4.12		2026-07-28
		15	Biological evaluation	VCu intra-uterine devices GB 11235-2006 4.13		2026-07-28
32	Copper-bearing contraceptive intrauterine devices	1	Partial items	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021	Except for X-ray detectability	2026-07-28
		2	shape	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021 5.2		2026-07-28
		3	measurement	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021 5.3		2026-07-28
		4	pulling force	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021 5.4		2026-07-28
		5	Deformation recovery	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021 5.5		2026-07-28
		6	barium sulfate content	Copper-bearing contraceptive intrauterine devices-Requirements and tests GB11236-2021 5.7		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
33	Vascular stents	1	Partial items	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016	Except for visibility, MRI safety and compatibility	2026-07-28
		2	Size	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 4.2	Use only when quoted or requested by the customer	2026-07-28
		3	Material	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 7	Use only when quoted or requested by the customer	2026-07-28
		4	Bond strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.2	Use only when quoted or requested by the customer	2026-07-28
		5	Component size compatibility	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.3	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Size	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.4	Use only when quoted or requested by the customer	2026-07-28
		7	Remove force	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.5	Use only when quoted or requested by the customer	2026-07-28
		8	Bending/Discounting	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.6	Use only when quoted or requested by the customer	2026-07-28
		9	Profile/diameter testing	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.7	Use only when quoted or requested by the customer	2026-07-28
		10	Pushability	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.8	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.9	Use only when quoted or requested by the customer	2026-07-28
		12	Torsion	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.10	Use only when quoted or requested by the customer	2026-07-28
		13	Torsional bonding strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.11	Use only when quoted or requested by the customer	2026-07-28
		14	traceability	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.1.12	Use only when quoted or requested by the customer	2026-07-28
		15	Bond strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.2	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Balloon filling time	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.3	Use only when quoted or requested by the customer	2026-07-28
		17	Balloon decompression time	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.4	Use only when quoted or requested by the customer	2026-07-28
		18	Rated burst pressure of balloon	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.5	Use only when quoted or requested by the customer	2026-07-28
		19	Balloon rated fatigue	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.6	Use only when quoted or requested by the customer	2026-07-28
		20	Component size compatibility	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.7	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		21	Size	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.8	Use only when quoted or requested by the customer	2026-07-28
		22	Remove force	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.9	Use only when quoted or requested by the customer	2026-07-28
		23	Dog bone effect	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.10	Use only when quoted or requested by the customer	2026-07-28
		24	release force	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.11	Use only when quoted or requested by the customer	2026-07-28
		25	simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.2.12	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		26	Bond strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.2	Use only when quoted or requested by the customer	2026-07-28
		27	Component size compatibility	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.3	Use only when quoted or requested by the customer	2026-07-28
		28	Dimensional verification	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.4	Use only when quoted or requested by the customer	2026-07-28
		29	Bending/Discounting	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.5	Use only when quoted or requested by the customer	2026-07-28
		30	simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.6	Use only when quoted or requested by the customer	2026-07-28

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		№	Item/ Parameter			
		31	Torsional bonding strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.7	Use only when quoted or requested by the customer	2026-07-28
		32	Tensile strength of pipes	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.3.8	Use only when quoted or requested by the customer	2026-07-28
		33	Biological evaluation	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.4	Use only when quoted or requested by the customer	2026-07-28
		34	Dimensional compatibility	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.5.2	Use only when quoted or requested by the customer	2026-07-28
		35	Dimensional verification	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.5.3	Use only when quoted or requested by the customer	2026-07-28

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		№	Item/ Parameter			
		36	Hemostatic evaluation	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.5.5.4	Use only when quoted or requested by the customer	2026-07-28
		37	The relationship between bracket length and diameter	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.1.2	Use only when quoted or requested by the customer	2026-07-28
		38	Contour effect/bell mouth	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.1.3	Use only when quoted or requested by the customer	2026-07-28
		39	Simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.1.4	Use only when quoted or requested by the customer	2026-07-28
		40	Wall adhesion performance	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.2	Use only when quoted or requested by the customer	2026-07-28

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		№	Item/ Parameter			
		41	Radial anti extrusion performance	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.3	Use only when quoted or requested by the customer	2026-07-28
		42	Resistance to parallel plate extrusion performance	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.4	Use only when quoted or requested by the customer	2026-07-28
		43	Local extrusion	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.5	Use only when quoted or requested by the customer	2026-07-28
		44	Radial strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.6	Use only when quoted or requested by the customer	2026-07-28
		45	Retract	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.7	Use only when quoted or requested by the customer	2026-07-28

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		№	Item/ Parameter			
		46	Simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.2.8	Use only when quoted or requested by the customer	2026-07-28
		47	Immediate coating integrit	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.2	Use only when quoted or requested by the customer	2026-07-28
		48	Coating dimensions and other coating parameters (Such as porosity, density distribution, mass)	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.3	Use only when quoted or requested by the customer	2026-07-28
		49	corrosiveness	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.4	Use only when quoted or requested by the customer	2026-07-28
		50	Fatigue durability performance test	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.5.4	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		51	Durability of coating	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.5.5	Use only when quoted or requested by the customer	2026-07-28
		52	Coating particle generation	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.5.6	Use only when quoted or requested by the customer	2026-07-28
		53	Visual inspection	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.3.6	Use only when quoted or requested by the customer	2026-07-28
		54	Dimensional verification	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.4.2	Use only when quoted or requested by the customer	2026-07-28
		55	The relationship between stent diameter and balloon filling pressure	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.4.3	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		56	Retract	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.4.4	Use only when quoted or requested by the customer	2026-07-28
		57	Simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.4.5	Use only when quoted or requested by the customer	2026-07-28
		58	The relationship between bracket length and diameter	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.4.6	Use only when quoted or requested by the customer	2026-07-28
		59	Radial anti extrusion performance	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.2	Use only when quoted or requested by the customer	2026-07-28
		60	Resistance to parallel plate extrusion performance	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.3	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		61	Bending/Breaking	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.4	Use only when quoted or requested by the customer	2026-07-28
		62	Local extrusion	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.5	Use only when quoted or requested by the customer	2026-07-28
		63	Radial strength	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.6	Use only when quoted or requested by the customer	2026-07-28
		64	Simulated use	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.7	Use only when quoted or requested by the customer	2026-07-28
		65	Blank surface area of bracket and outer surface area of bracket	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.5.8	Use only when quoted or requested by the customer	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		66	Biological evaluation	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.7	Use only when quoted or requested by the customer	2026-07-28
		67	Drug-eluting	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 8.6.8.2	Use only when quoted or requested by the customer	2026-07-28
		68	Sterilization Residue	Cardiovascular implants Endovascular devices—Part 2:Vascular stents YY/T 0663.2-2016 11.3	Use only when quoted or requested by the customer	2026-07-28
34		1				2026-07-28
		2				2026-07-28
		3	Tests for carcinogenicity	Biological evaluation of medical devices-Part3:Tests for genotoxicity,carcinogenicity and reproductive toxicity GB/T16886.3-2019		2026-07-28
		4	Tests for reproductive toxicity	Biological evaluation of medical devices-Part3:Tests for genotoxicity,carcinogenicity and reproductive toxicity GB/T16886.3-2019		2026-07-28
		5	Selection of tests for interactions with blood	Biological evaluation of medical devices-Part4:Selection of tests fou interactions with biood GB/T16886.4-2022	Except for in vivo experiment	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					s	
		6	Tests for in vitro cytotoxicity	Biological evaluation of medical devices-Part 5:Tests for in vitro cytotoxicity GB/T 16886.5-2017		2026-07-28
		7				2026-07-28
		8	Colony formation cytotoxicity test	Biological evaluation of medical devices-Part 5:Tests for in vitro cytotoxicity GB/T 16886.5-2017		2026-07-28
		9	MTT cytotoxicity test	Biological evaluation of medical devices-Part 5:Tests for in vitro cytotoxicity GB/T 16886.5-2017		2026-07-28
		10	XTT cytotoxicity test	Biological evaluation of medical devices-Part 5:Tests for in vitro cytotoxicity GB/T 16886.5-2017		2026-07-28
		11	Tests for local effects after implantation	Biological evaluation of medical devices-Part6:Tests for local effects after implantation GB/T16886.6-2022		2026-07-28
		12	Tests for local effects after subcutaneous tissue implantation	Biological evaluation of medical devices-Part6:Tests for local effects after implantation GB/T16886.6-2022		2026-07-28
		13				2026-07-28
		14	Tests for local effects after implantation in brain	Biological evaluation of medical devices-Part6:Tests for local effects after implantation GB/T16886.6-2022		2026-07-28
		15	Framework for identification and quantification of potential degradation products	Biological evaluation of medical devices-Part9:Framework for identification and quantification of potential degradation products GB/T16886.9-2022		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Ethylene oxide sterilization residuals	Biological evaluation of medical devices-Part 7:Ethylene oxide sterilization residuals GB/T16886.7-2015		2026-07-28
		17	Tests for local effects after implantation in muscle	Biological evaluation of medical devices-Part6:Tests for local effects after implantation GB/T16886.6-2022		2026-07-28
		18	Tests for kin sensitization	Biological evaluation of medical devices-Part10:Tests for skin sensitization GB/T 16886.10-2024	Except for local lymph node test in mice	2026-07-28
		19	Tests for systemic toxicity	Biological evaluation of medical devices-Part11:Tests for systemic toxicity GB/T 16886.11-2021		2026-07-28
		20	Tests for acute systemic toxicity	Biological evaluation of medical devices-Part11:Tests for systemic toxicity GB/T 16886.11-2021		2026-07-28
		21	Tests for subacute systemic toxicity	Biological evaluation of medical devices-Part11:Tests for systemic toxicity GB/T 16886.11-2021		2026-07-28
		22	Tests for subchronic systemic toxicity	Biological evaluation of medical devices-Part11:Tests for systemic toxicity GB/T 16886.11-2021		2026-07-28
		23	Tests for chronic systemic toxicity	Biological evaluation of medical devices-Part11:Tests for systemic toxicity GB/T 16886.11-2021		2026-07-28
		24	Subacute systemic toxicity test via enteral and parenteral dual routes	Biological evaluation of medical devices-Part11:Tests for systemic toxicity GB/T 16886.11-2021		2026-07-28
		25	Maximum dose test in guinea pigs	Biological evaluation of medical devices-Part10:Tests for skin sensitization GB/T 16886.10-2024 6.5		2026-07-28
		26	Sample preparation and reference	Biological evaluation of medical devices-Part12:Sample preparation and reference materials GB/T16886.12-2023		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			materials			
		27	Occlusion patch test	Biological evaluation of medical devices-Part10:Tests for skin sensitization GB/T 16886.10-2024 6.6		2026-07-28
		28	Identification and quantification of degradation products from polymeric medical devices	Biological evaluation of medical devices-Part 13：Identification and quantification of degradation products from polymeric medical devices GB/T16886.13-2017		2026-07-28
		29	Identification and quantification of degradation products from ceramics	Biological evaluation of medical devices-Part 14：Identification and quantification of degradation products from ceramics GB/T16886.14-2003		2026-07-28
		30	Identification and quantification of degradation products from metals and alloys	Biological evaluation of medical devices-Part15:Identification and quantification of degradation products from metals and alloys GB/T16886.15-2022		2026-07-28
		31	Toxicokinetic study design for degradation products and leachables	Biological evaluation of medical devices-Part16:Toxicokinetic study design for degradation products and leachables GB/T16886.16-2021		2026-07-28
		32	Chemical characterization of medical device materials	Biological evaluation of medical devices-Part18:Chemical characterization of medical device materials within a risk management process GB/T16886.18-2022	Only material analysis using gas chromatography, liquid	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					chromatography, ion chromatography, mass spectrometry, nuclear magnetic resonance spectroscopy, atomic absorption, ultraviolet, infrared, X-ray fluorescence, differential scanning calorimetry, oxygen nitrogen hydrogen analysis, carbon sulfur analysis, electrophoresis, protein determination,	

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					titration, and colorimetric analysis methods	
		33	Physico-chemical, morphological and topographical characterization of materials	Biological evaluation of medical devices-Part19:Physico-chemical,morphological and topographical characterization of materials GB/T16886.19-2022	Only surface shape and form, hardness, roughness, chemical identification of particle, protein adsorption	2026-07-28
		34	Principles and methods for immunotoxicology testing of medical devices	Biological evaluation of medical devices-Part20: Principles and methods for immunotoxicology testing of medical devices GB/T 16886.20-2015		2026-07-28
		35	product of complement activation	Test for complement activation of medical devices- Part 3: Assay for the product of complement activation (C3 and SC5b-9) YY/T 0878.3-2019		2026-07-28
		36	Biological evaluation of absorbable medical devices	Biological evaluation of absorbable medical devices—Part 1:Guidance for absorbable implants YY/T 1775.1-2021		2026-07-28
		37	implantation	Tissue engineering medical products-Standard practice for		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			assessment of absorbable medical products	implantation assessment of absorbable/resorbable biomaterials YY/T 1576-2017		
		38	Tests for irritation	Biological evaluation of medical devices——Part23：Tests for irritation GB/T 16886.23-2023	Except for human skin irritation test	2026-07-28
		39	Tests for hemolysis	Tests for hemolysis of medical devices—Part 1：Material induced hemolysis assay YY/T 1651.1-2019		2026-07-28
		40	Tests for irritation in vitro	Biological evaluation of medical devices——Part23：Tests for irritation GB/T 16886.23-2023 6		2026-07-28
		41	Flow cytometry for cell subset analysis	Immunogenic evaluation method of medical devices--Part 6: Determination of animal sleen lymphocyte subsets by flow cytometry YY/T 1465.6-2019		2026-07-28
		42	Tests for irritation in vivo	Biological evaluation of medical devices——Part23：Tests for irritation GB/T 16886.23-2023 7		2026-07-28
		43		Immunogenic evaluation method of medical devices--Part 7: Liquid phase multiplex protein quantification technique by flow cytometry YY/T 1465.7-2021		2026-07-28
		44	In Vitro skin irritation test	In Vitro skin irritation test for medical devices YY/T 1808-2021		2026-07-28
35	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements	1	Partial items	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017	Except for X-ray detectability	2026-07-28
		2	External Surface	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017 4.4		2026-07-28
		3	Corrosion resistance	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017 4.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Peak tensile force	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017 4.6		2026-07-28
		5	Leakage	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017 4.7		2026-07-28
		6	seat	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017 4.8		2026-07-28
		7	Flow	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017 4.9		2026-07-28
		8	Power injection	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017 4.10		2026-07-28
		9	Lateral aperture	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017 4.11		2026-07-28
		10	End head end	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017 4.12		2026-07-28
		11	Identification of nominal size	Intravascular catheters-Sterile and single-use catheters-Part 1:General requirements YY 0285.1－2017 5		2026-07-28
36	Sterile, single-use intravascular catheters-Part 2：Angiographic catheters	1	Partial items	Sterile, single-use intravascular catheters-Part 2：Angiographic catheters YY 0285.2-1999	Except for X-ray detectability	2026-07-28
		2	Identification of nominal size	Sterile, single-use intravascular catheters-Part 2：Angiographic catheters YY 0285.2-1999 4.3		2026-07-28
		3	Tip configuration	Sterile, single-use intravascular catheters-Part 2：Angiographic catheters YY 0285.2-1999 4.4.1		2026-07-28
		4	No leakage and damage under high static pressure	Sterile, single-use intravascular catheters-Part 2：Angiographic catheters YY 0285.2-1999 4.4.2		2026-07-28
		5	Lateral aperture	Sterile, single-use intravascular catheters-Part 2：Angiographic catheters YY 0285.2-1999 4.4.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
37	Intravascular catheters-Sterile and single-use catheters—Part 3: Central venous catheters	1	All items	Intravascular catheters-Sterile and single-use catheters—Part 3: Central venous catheters YY 0285.3-2017	Except for X-ray detectability	2026-07-28
		2	Distance identification	Intravascular catheters-Sterile and single-use catheters—Part 3: Central venous catheters YY 0285.3-2017 4.2		2026-07-28
		3	Lumen identification	Intravascular catheters-Sterile and single-use catheters—Part 3: Central venous catheters YY 0285.3-2017 4.3		2026-07-28
		4	Peak tensile force	Intravascular catheters-Sterile and single-use catheters—Part 3: Central venous catheters YY 0285.3-2017 4.4		2026-07-28
38	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters	1	Partial items	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017	Except for X-ray detectability	2026-07-28
		2	Identification of nominal specifications	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017 4.3		2026-07-28
		3	Rated Burst Pressure (RBP) of Balloon	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017 4.4.1		2026-07-28
		4	Balloon fatigue, No leakage or damage during charging	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017 4.4.2		2026-07-28
		5	Balloon decompression time	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017 4.4.3		2026-07-28
		6	The relationship between balloon diameter and filling pressure	Intravascular catheters—Sterile and single-use catheters—Part 4 : Balloon dilatation catheters YY 0285.4-2017 4.4.4		2026-07-28

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SCHEDULE OF ACCREDITATION FOR THE LABORATORY

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
39	Sterile, single-use intravascular catheters-Over-needle peripheral catheters	1	All items	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018		2026-07-28
		2	Multicavity catheter	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.2		2026-07-28
		3	Color code	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.1		2026-07-28
		4	Conduit Assembly	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.2		2026-07-28
		5	Material	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.3.1		2026-07-28
		6	Needle tip	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.3.2		2026-07-28
		7	Needle holder	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.3.3		2026-07-28
		8	Connection strength between needle tube and needle base	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.3.4		2026-07-28
		9	Exhaust connector	Intravascular catheters--Sterile and single-use catheters-Part 5:Over-needle peripheral catheters YY 0285.5-2018 4.3.4		2026-07-28
40	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers	1	Partial items	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020	Except for X-ray detectability	2026-07-28
		2	surface	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 4.3		2026-07-28
		3	corrosion resistance	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 4.4		2026-07-28
		4	Specification identification	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 5.2		2026-07-28

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SCHEDULE OF ACCREDITED ITEMS

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		№	Item/ Parameter			
		5	Needle tip	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 5.3		2026-07-28
		6	taper joint	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 5.4.1		2026-07-28
		7	Connection strength between needle tube and needle base	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 5.4.2		2026-07-28
		8	head end	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 6.2		2026-07-28
		9	Peak tensile force	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 6.3		2026-07-28
		10	seat	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 6.4		2026-07-28
		11	Specification identification	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 6.5		2026-07-28
		12	Specification identification	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 7.2		2026-07-28
		13	No leakage in the sheath of the catheter	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 7.3		2026-07-28
		14	No leakage of hemostasis valve	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 7.4		2026-07-28
		15	seat	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 7.5		2026-07-28
		16	Peak tensile force	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 7.6		2026-07-28
		17	Specification identification	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 8.2		2026-07-28
		18	security thread	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 8.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	Rupture test	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 8.4		2026-07-28
		20	Bending test	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 8.5		2026-07-28
		21	Peak tension of guide wire	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 8.6		2026-07-28
		22	Specification identification	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 9.3		2026-07-28
		23	seat	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 9.3		2026-07-28
		24	Connection strength between needle tube and needle base	Accessory devices for sterile single-use intravascular catheters-Part 1 :Introducers YY 0450.1-2020 11		2026-07-28
41	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters	1	Partial items	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003	Except for X-ray detectability	2026-07-28
		2	surface	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.3		2026-07-28
		3	Breaking force	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.4		2026-07-28
		4	Ruhr joint	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.5		2026-07-28
		5	outside diameter	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.6		2026-07-28

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		№	Item/ Parameter			
		6	active length	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.7		2026-07-28
		7	Color code	Accessory devices for sterile single-use intravascular catheters-Part 2:Obturators for over-needle peripheral catheters YY 0450.2-2003 4.8		2026-07-28
42	Infusion sets for single use	1	All items	Infusion sets for single use-Gravity feed GB 8368-2018		2026-07-28
		2	Particle contamination	Infusion sets for single use-Gravity feed GB 8368-2018 6.1		2026-07-28
		3	Leakage	Infusion sets for single use-Gravity feed GB 8368-2018 6.2		2026-07-28
		4	tensile strength	Infusion sets for single use-Gravity feed GB 8368-2018 6.3		2026-07-28
		5	Bottle stopper puncture device	Infusion sets for single use-Gravity feed GB 8368-2018 6.4		2026-07-28
		6	Air intake device	Infusion sets for single use-Gravity feed GB 8368-2018 6.5		2026-07-28
		7	piping	Infusion sets for single use-Gravity feed GB 8368-2018 6.6		2026-07-28
		8	Liquid filter	Infusion sets for single use-Gravity feed GB 8368-2018 6.7		2026-07-28
		9	Drip bucket and dropper	Infusion sets for single use-Gravity feed GB 8368-2018 6.8		2026-07-28
		10	regulator	Infusion sets for single use-Gravity feed GB 8368-2018 6.9		2026-07-28
		11	Infusion flow rate	Infusion sets for single use-Gravity feed GB 8368-2018 6.10		2026-07-28
		12	Injection parts	Infusion sets for single use-Gravity feed GB 8368-2018 6.11		2026-07-28
		13	Outer cone joint	Infusion sets for single use-Gravity feed GB 8368-2018 6.12		2026-07-28

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		№	Item/ Parameter			
		14	protective sheath	Infusion sets for single use-Gravity feed GB 8368-2018 6.13		2026-07-28
		15	Reducing Substances (Readily oxidation substance)	Infusion sets for single use-Gravity feed GB 8368-2018 7.1		2026-07-28
		16	Metal Ions	Infusion sets for single use-Gravity feed GB 8368-2018 7.2		2026-07-28
		17	Acid-Base Titration	Infusion sets for single use-Gravity feed GB 8368-2018 7.3		2026-07-28
		18	Residue on Evaporation	Infusion sets for single use-Gravity feed GB 8368-2018 7.4		2026-07-28
		19	Ultraviolet Absorbance of Extraction Liquid	Infusion sets for single use-Gravity feed GB 8368-2018 7.5		2026-07-28
		20	Ethylene Oxide Residue	Infusion sets for single use-Gravity feed GB 8368-2018 7.6		2026-07-28
		21	Sterility	Infusion sets for single use-Gravity feed GB 8368-2018 8.2		2026-07-28
		22	Pyrogen	Infusion sets for single use-Gravity feed GB 8368-2018 8.3		2026-07-28
		23	Hemolysis test	Infusion sets for single use-Gravity feed GB 8368-2018 8.4		2026-07-28
		24	Biological evaluation	Infusion sets for single use-Gravity feed GB 8368-2018 8.5		2026-07-28
43	Transfusion sets for single use	1	All items	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019		2026-07-28
		2	Particle contamination	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.1		2026-07-28
		3	Leakage	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Tensile strength	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.3		2026-07-28
		5	Transfusion faucet puncture set	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.4		2026-07-28
		6	piping	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.5		2026-07-28
		7	Blood and blood component filters	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.6		2026-07-28
		8	Drip bucket and dropper	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.7		2026-07-28
		9	regulator	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.8		2026-07-28
		10	Flow rate of blood and blood components	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.9		2026-07-28
		11	Injection parts	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.10		2026-07-28
		12	Outer cone joint	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.11		2026-07-28
		13	protective sheath	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 5.12		2026-07-28
		14	Reducing Substances (Readily oxidation substance)	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.1		2026-07-28
		15	Metal Ions	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.2		2026-07-28
		16	Acid-Base Titration	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.3		2026-07-28
		17	Residue on Evaporation	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Ultraviolet Absorbance of Extraction Liquid	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.5		2026-07-28
		19	Ethylene Oxide Residue	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 6.6		2026-07-28
		20	Sterility	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 7.2		2026-07-28
		21	Pyrogen	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 7.3		2026-07-28
		22	Hemolysis test	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 7.4		2026-07-28
		23	Biological evaluation	Transfusion sets for single use-Part 1 :Gravity feed GB 8369.1-2019 7.5		2026-07-28
44	Infusion sets for single use with micropore filters	1	All items	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019		2026-07-28
		2	design	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.1		2026-07-28
		3	Particle contamination	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.2		2026-07-28
		4	Requirements for filtration performance of sterilization grade liquid filters	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.3		2026-07-28
		5	Nominal bore 1.2 μm Filtration performance requirements of solution filter	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Nominal bore 2.0 μm~5.0 μ m Liquid filter filtration performance requirements	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.5		2026-07-28
		7	Vent (if any)	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.2.6		2026-07-28
		8	Infusion flow rate	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 7.3		2026-07-28
		9	Chemical Requirements	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 8		2026-07-28
		10	Biological requirements	Infusion sets for special purpose-Part 1 :Infusion sets for single use with micropore filters YY 0286.1-2019 9		2026-07-28
45	Burette-type infusion sets for single use-Gravity feed	1	All items	Special infusion sets-Part 2：Burette-type infusion sets for single use-Gravity feed YY 0286.2-2006		2026-07-28
		2	design	Special infusion sets-Part 2：Burette-type infusion sets for single use-Gravity feed YY 0286.2-2006 6.2		2026-07-28
		3	Burette capacity	Special infusion sets-Part 2：Burette-type infusion sets for single use-Gravity feed YY 0286.2-2006 6.3		2026-07-28
		4	scale	Special infusion sets-Part 2：Burette-type infusion sets for single use-Gravity feed YY 0286.2-2006 6.4		2026-07-28
		5	Chemical Requirements	Special Infusion sets-Part 2 :Burette-Type Infusion sets for single use- Gravity feed YY 0286.2-2006 7		2026-07-28
		6	Biological requirements	Special Infusion sets-Part 2 :Burette-Type Infusion sets for single use- Gravity feed YY 0286.2-2006 8		2026-07-28
46	A.V.fistula needle sets for single use	1	All items	A.V.fistula needle sets for single use YY/T 0328-2015		2026-07-28
		2	particle contamination	A.V.fistula needle sets for single use YY/T 0328-2015 5.1		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Sealing performance	A.V.fistula needle sets for single use YY/T 0328-2015 5.2		2026-07-28
		4	connection strength	A.V.fistula needle sets for single use YY/T 0328-2015 5.3		2026-07-28
		5	flow	A.V.fistula needle sets for single use YY/T 0328-2015 5.4		2026-07-28
		6	hose	A.V.fistula needle sets for single use YY/T 0328-2015 5.5		2026-07-28
		7	puncture needle	A.V.fistula needle sets for single use YY/T 0328-2015 5.6		2026-07-28
		8	Stop clamp	A.V.fistula needle sets for single use YY/T 0328-2015 5.7		2026-07-28
		9	Inner cone joint	A.V.fistula needle sets for single use YY/T 0328-2015 5.8		2026-07-28
		10	case	A.V.fistula needle sets for single use YY/T 0328-2015 5.9		2026-07-28
		11	Reducing Substances	A.V.fistula needle sets for single use YY/T 0328-2015 6.2		2026-07-28
		12	Metal Ions	A.V.fistula needle sets for single use YY/T 0328-2015 6.3		2026-07-28
		13	Acid-Base Titration	A.V.fistula needle sets for single use YY/T 0328-2015 6.4		2026-07-28
		14	Residue on Evaporation	A.V.fistula needle sets for single use YY/T 0328-2015 6.5		2026-07-28
		15	Ultraviolet Absorbance	A.V.fistula needle sets for single use YY/T 0328-2015 6.6		2026-07-28
		16	Ethylene Oxide Residue	A.V.fistula needle sets for single use YY/T 0328-2015 6.7		2026-07-28
		17	Biological evaluation	A.V.fistula needle sets for single use YY/T 0328-2015 7.1		2026-07-28
		18	Sterility	A.V.fistula needle sets for single use YY/T 0328-2015 7.2		2026-07-28

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		№	Item/ Parameter			
		19	Bacterial endotoxins	A.V.fistula needle sets for single use YY/T 0328-2015 7.3		2026-07-28
47	Conventional blood containers	1	All items	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020		2026-07-28
		2	size	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 4.1		2026-07-28
		3	air content	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.2		2026-07-28
		4	Pressure evacuation	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.3		2026-07-28
		5	Blood sample identification	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.4		2026-07-28
		6	Acquisition speed	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.5		2026-07-28
		7	Blood collection and transfer tubes	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.6		2026-07-28
		8	blood taking needle	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.7		2026-07-28
		9	Blood transfusion socket	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.8		2026-07-28

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		№	Item/ Parameter			
		10	hang	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 5.9		2026-07-28
		11	transparency	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.3		2026-07-28
		12	colour and lustre	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.4		2026-07-28
		13	thermal stability	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.5		2026-07-28
		14	Water vapor leakage	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.6		2026-07-28
		15	Anti leakage	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.7		2026-07-28
		16	particle contamination	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.2.8		2026-07-28
		17	Chemical requirements	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.3		2026-07-28
		18	Bological requirements	Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers GB 14232.1-2020 6.4		2026-07-28
48	Plunger seal of syringes for	1	All items	Plunger seal of syringes for single use YY/T 0243-2016		2026-07-28

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		№	Item/ Parameter			
	single use	2	appearance	Plunger seal of syringes for single use YY/T 0243-2016 5.1		2026-07-28
		3	Hardness (shore A)	Plunger seal of syringes for single use YY/T 0243-2016 5.2.1		2026-07-28
		4	compression set	Plunger seal of syringes for single use YY/T 0243-2016 5.2.2		2026-07-28
		5	Change rate of tensile strength	Plunger seal of syringes for single use YY/T 0243-2016 5.2.3		2026-07-28
		6	Change rate of elongation at break	Plunger seal of syringes for single use YY/T 0243-2016 5.2.4		2026-07-28
		7	pH	Plunger seal of syringes for single use YY/T 0243-2016 5.3.1		2026-07-28
		8	Extractable Metal Content	Plunger seal of syringes for single use YY/T 0243-2016 5.3.2		2026-07-28
		9	Reducing Substances	Plunger seal of syringes for single use YY/T 0243-2016 5.3.3		2026-07-28
		10	Ultraviolet Absorbance	Plunger seal of syringes for single use YY/T 0243-2016 5.3.4		2026-07-28
		11	Ash Content	Plunger seal of syringes for single use YY/T 0243-2016 5.3.5		2026-07-28
		12	Pyrogen	Plunger seal of syringes for single use YY/T 0243-2016 5.4.1		2026-07-28
		13	Cytotoxicity	Plunger seal of syringes for single use YY/T 0243-2016 5.4.2		2026-07-28
		14	Hemolysis test	Plunger seal of syringes for single use YY/T 0243-2016 5.4.3		2026-07-28
		15	Irritation	Plunger seal of syringes for single use YY/T 0243-2016 5.4.4		2026-07-28
		16	Sensitization	Plunger seal of syringes for single use YY/T 0243-2016 5.4.5		2026-07-28
		17	Acute systemic toxicity	Plunger seal of syringes for single use YY/T 0243-2016 5.4.6		2026-07-28

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49	Blood flow products for single use-General specification	1	All items	Blood flow products for single use-General specification GB/T 19335-2022		2026-07-28
		2	protective sheath	Blood flow products for single use-General specification GB/T 19335-2022 6.1		2026-07-28
		3	Injection parts	Blood flow products for single use-General specification GB/T 19335-2022 6.2		2026-07-28
		4	Connector	Blood flow products for single use-General specification GB/T 19335-2022 6.3		2026-07-28
		5	Blood and blood component filter screen	Blood flow products for single use-General specification GB/T 19335-2022 6.4		2026-07-28
		6	switch	Blood flow products for single use-General specification GB/T 19335-2022 6.5		2026-07-28
		7	Pressure monitoring connector/sensor protector	Blood flow products for single use-General specification GB/T 19335-2022 6.6		2026-07-28
		8	appearance	Blood flow products for single use-General specification GB/T 19335-2022 7.2.1		2026-07-28
		9	Tightness	Blood flow products for single use-General specification GB/T 19335-2022 7.2.2		2026-07-28
		10	Connection firmness	Blood flow products for single use-General specification GB/T 19335-2022 7.2.3		2026-07-28
		11	particle contamination	Blood flow products for single use-General specification GB/T 19335-2022 7.2.4		2026-07-28
		12	color code	Blood flow products for single use-General specification GB/T 19335-2022 7.2.5		2026-07-28
		13	color	Blood flow products for single use-General specification GB/T 19335-2022 7.3.2		2026-07-28
		14	reducing substance	Blood flow products for single use-General specification GB/T 19335-2022 7.3.3		2026-07-28

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		№	Item/ Parameter			
		15	metal ions	Blood flow products for single use-General specification GB/T 19335-2022 7.3.4		2026-07-28
		16	PH	Blood flow products for single use-General specification GB/T 19335-2022 7.3.5		2026-07-28
		17	Evaporation residue	Blood flow products for single use-General specification GB/T 19335-2022 7.3.6		2026-07-28
		18	Ultraviolet absorption	Blood flow products for single use-General specification GB/T 19335-2022 7.3.7		2026-07-28
		19	ethylene oxide residue	Blood flow products for single use-General specification GB/T 19335-2022 7.4		2026-07-28
		20	sterility	Blood flow products for single use-General specification GB/T 19335-2022 7.5.2		2026-07-28
		21	bacterial endotoxin	Blood flow products for single use-General specification GB/T 19335-2022 7.5.3		2026-07-28
		22	haemocompatible	Blood flow products for single use-General specification GB/T 19335-2022 7.5.4		2026-07-28
50	Single-use containers for human venous blood specimen collection	1	All items	Single-use containers for human venous blood specimen collection YY/T 0314-2021		2026-07-28
		2	Suction volume	Single-use containers for human venous blood specimen collection YY/T 0314-2021 5		2026-07-28
		3	structure	Single-use containers for human venous blood specimen collection YY/T 0314-2021 7		2026-07-28
		4	Sterility and specific microbial status	Single-use containers for human venous blood specimen collection YY/T 0314-2021 8		2026-07-28
		5	additive	Single-use containers for human venous blood specimen collection YY/T 0314-2021 9		2026-07-28
		6	Identification of collection containers	Single-use containers for human venous blood specimen collection YY/T 0314-2021 11		2026-07-28
51	Infusion sets for single use-	1	All items	Infusion sets for single use-Gravity feed GB 8368-2018		2026-07-28

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	Gravity feed	2	Particle contamination	Infusion sets for single use-Gravity feed GB 8368-2018 6.1		2026-07-28
		3	leakage	Infusion sets for single use-Gravity feed GB 8368-2018 6.2		2026-07-28
		4	tensile strength	Infusion sets for single use-Gravity feed GB 8368-2018 6.3		2026-07-28
		5	Bottle stopper puncture device	Infusion sets for single use-Gravity feed GB 8368-2018 6.4		2026-07-28
		6	Air intake device	Infusion sets for single use-Gravity feed GB 8368-2018 6.5		2026-07-28
		7	piping	Infusion sets for single use-Gravity feed GB 8368-2018 6.6		2026-07-28
		8	Liquid filter	Infusion sets for single use-Gravity feed GB 8368-2018 6.7		2026-07-28
		9	Drip bucket and dropper	Infusion sets for single use-Gravity feed GB 8368-2018 6.8		2026-07-28
		10	regulator	Infusion sets for single use-Gravity feed GB 8368-2018 6.9		2026-07-28
		11	Infusion flow rate	Infusion sets for single use-Gravity feed GB 8368-2018 6.10		2026-07-28
		12	Injection parts	Infusion sets for single use-Gravity feed GB 8368-2018 6.11		2026-07-28
		13	Outer cone joint	Infusion sets for single use-Gravity feed GB 8368-2018 6.12		2026-07-28
		14	protective sheath	Infusion sets for single use-Gravity feed GB 8368-2018 6.13		2026-07-28
		15	Reducing Substances	Infusion sets for single use-Gravity feed GB 8368-2018 7.1		2026-07-28
		16	Metal Ions	Infusion sets for single use-Gravity feed GB 8368-2018 7.2		2026-07-28
		17	Acid-Base Titration	Infusion sets for single use-Gravity feed GB 8368-2018 7.3		2026-07-28

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		18	Residue on Evaporation	Infusion sets for single use-Gravity feed GB 8368-2018 7.4		2026-07-28
		19	Ultraviolet Absorbance of Extraction Liquid	Infusion sets for single use-Gravity feed GB 8368-2018 7.5		2026-07-28
		20	Ethylene Oxide Residue	Infusion sets for single use-Gravity feed GB 8368-2018 7.6		2026-07-28
		21	Sterility	Infusion sets for single use-Gravity feed GB 8368-2018 8.2		2026-07-28
		22	Pyrogen	Infusion sets for single use-Gravity feed GB 8368-2018 8.3		2026-07-28
		23	Hemolysis test	Infusion sets for single use-Gravity feed GB 8368-2018 8.4		2026-07-28
		24	Biological evaluation	Infusion sets for single use-Gravity feed GB 8368-2018 8.5		2026-07-28
52	Human blood containers for UV transmission therapy for single use	1	All items	Human blood containers for UV transmission therapy for single use YY 0327-2002		2026-07-28
		2	materials	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.1		2026-07-28
		3	structure	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.2		2026-07-28
		4	appearance	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.3		2026-07-28
		5	Particle contamination	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.1		2026-07-28
		6	tightness	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.2		2026-07-28
		7	connection strength	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.3		2026-07-28
		8	UV transmittance	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.4		2026-07-28

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		№	Item/ Parameter			
		9	intake pipe	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.5		2026-07-28
		10	Suspension device	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.6		2026-07-28
		11	protective sheath;	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.4.7		2026-07-28
		12	Reducing Substances	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.1		2026-07-28
		13	Metal Ions	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.2		2026-07-28
		14	pH	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.3		2026-07-28
		15	Residue on Evaporation	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.4		2026-07-28
		16	Ultraviolet Absorbance	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.5		2026-07-28
		17	Color	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.6		2026-07-28
		18	Ethylene Oxide Residue	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.5.7		2026-07-28
		19	Sterility	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.6.1		2026-07-28
		20	Pyrogen	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.6.2		2026-07-28
		21	Hemolysis test	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.6.3		2026-07-28
		22	Acute systemic toxicity	Human blood containers for UV transmission therapy for single use YY 0327-2002 4.6.4		2026-07-28
53	Implantable drug-supplying	1	Partial items	Implantable drug-supplying device YY 0332-2011	Except for X-ray	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	device				detectability	
		2	General requirements	Implantable drug-supplying device YY 0332-2011 5.1		2026-07-28
		3	appearance	Implantable drug-supplying device YY 0332-2011 5.2.1		2026-07-28
		4	puncture resistance	Implantable drug-supplying device YY 0332-2011 5.2.2.1		2026-07-28
		5	Puncture of chips	Implantable drug-supplying device YY 0332-2011 5.2.2.2		2026-07-28
		6	Puncture limit	Implantable drug-supplying device YY 0332-2011 5.2.2.3		2026-07-28
		7	Bubble discharge	Implantable drug-supplying device YY 0332-2011 5.2.2.4		2026-07-28
		8	size	Implantable drug-supplying device YY 0332-2011 5.2.3.1		2026-07-28
		9	Bending resistance	Implantable drug-supplying device YY 0332-2011 5.2.3.2		2026-07-28
		10	Dynamic fracture strength	Implantable drug-supplying device YY 0332-2011 5.2.4		2026-07-28
		11	Tightness	Implantable drug-supplying device YY 0332-2011 5.2.5		2026-07-28
		12	Sterility	Implantable drug-supplying device YY 0332-2011 5.3		2026-07-28
		13	Bacterial endotoxins	Implantable drug-supplying device YY 0332-2011 5.4		2026-07-28
		14	Ethylene Oxide Residue	Implantable drug-supplying device YY 0332-2011 5.5		2026-07-28
54	Soft-tissue expander device	1	All items	Soft-tissue expander device YY 0333-2010		2026-07-28
		2	shell	Soft-tissue expander device YY 0333-2010 9.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Pipeline shell connection strength	Soft-tissue expander device YY 0333-2010 9.3		2026-07-28
		4	Injection seat performance	Soft-tissue expander device YY 0333-2010 9.4		2026-07-28
		5	Expansion resistance	Soft-tissue expander device YY 0333-2010 9.5		2026-07-28
		6	Joint strength	Soft-tissue expander device YY 0333-2010 9.6		2026-07-28
		7	Needle punched limit piece	Soft-tissue expander device YY 0333-2010 9.7		2026-07-28
		8	Adhesive joint	Soft-tissue expander device YY 0333-2010 9.8		2026-07-28
		9	Ethylene Oxide Residue	Soft-tissue expander device YY 0333-2010 10.2		2026-07-28
55	General specification for surgical implants made of silicone elastomer	1	All items	General specification for surgical implants made of silicone elastomer YY/T 0334-2022		2026-07-28
		2	appearance	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 4		2026-07-28
		3	biological evaluation	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.2		2026-07-28
		4	Drying loss	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.3.1		2026-07-28
		5	Trace element	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.3.2		2026-07-28
		6	Identify	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.3.3		2026-07-28
		7	Solution appearance	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.1		2026-07-28
		8	Evaporation residue	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	pH	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.3		2026-07-28
		10	Catalyst residue	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.4		2026-07-28
		11	Reducing substance	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.5		2026-07-28
		12	Ultraviolet absorption	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.6		2026-07-28
		13	Heavy metal	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 5.4.7		2026-07-28
		14	Sterility	General specification for surgical implants made of silicone elastomer YY/T 0334-2022 6		2026-07-28
56	Cervix dilator	1	All items	Cervix dilator YY 0091-2013		2026-07-28
		2	appearance	Cervix dilator YY 0091-2013 4.1		2026-07-28
		3	size	Cervix dilator YY 0091-2013 4.2		2026-07-28
		4	roughness	Cervix dilator YY 0091-2013 4.3		2026-07-28
		5	cladding material	Cervix dilator YY 0091-2013 4.4		2026-07-28
		6	Corrosion Resistance	Cervix dilator YY 0091-2013 4.5		2026-07-28
57	Sterile vaginal dilator for single use	1	All items	Sterile vaginal dilator for single use YY 0336-2020		2026-07-28
		2	appearance	Sterile vaginal dilator for single use YY 0336-2020 4.1		2026-07-28
		3	measurement	Sterile vaginal dilator for single use YY 0336-2020 4.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	usability	Sterile vaginal dilator for single use YY 0336-2020 4.3		2026-07-28
		5	physical quantity	Sterile vaginal dilator for single use YY 0336-2020 4.4		2026-07-28
		6	sterility	Sterile vaginal dilator for single use YY 0336-2020 4.5		2026-07-28
		7	ethylene oxide residue	Sterile vaginal dilator for single use YY 0336-2020 4.6		2026-07-28
		8	biological evaluation	Sterile vaginal dilator for single use YY 0336-2020 4.7		2026-07-28
58	Commonly-used tubes and connectors	1	All items	Tracheal tubes Part 1:- Commonly-used tubes and connectors YY 0337.1-2002		2026-07-28
		2	Specification identification	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.1		2026-07-28
		3	size	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.2		2026-07-28
		4	bevel	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.4		2026-07-28
		5	cuff	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.5		2026-07-28
		6	cuff inflating fube	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.6		2026-07-28
		7	tube radian	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 4.7		2026-07-28
		8	Murphy hole size	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 5.1		2026-07-28
		9	Murphy hole position	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 5.2		2026-07-28
		10	Sterility	Tracheal tubes Part 1:-Commonly-used tubes and connectors YY 0337.1-2002 6.1		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
59	Cole type tube	1	All items	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002		2026-07-28
		2	size	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002 7		2026-07-28
		3	bevel	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002 8		2026-07-28
		4	shoulder	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002 9		2026-07-28
		5	tube radian	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002 10		2026-07-28
		6	sign	Tracheal tubes-Part2: Cole type tube YY 0337.2-2002 11		2026-07-28
60	Anaesthetic and respiratory equipment-Conical connectors-Part 1：Cones and sockets	1	All items	Anaesthetic and respiratory equipment-Conical connectors-Part 1：Cones and sockets YY/T 1040.1-2015		2026-07-28
		2	common requirements	Anaesthetic and respiratory equipment-Conical connectors-Part 1：Cones and sockets YY/T 1040.1-2015 4.1		2026-07-28
		3	additional requirements for 22mm outer conical connectors	Anaesthetic and respiratory equipment-Conical connectors-Part 1：Cones and sockets YY/T 1040.1-2015 4.2		2026-07-28
		4	additional requirements for 8.5mm conical connectors	Anaesthetic and respiratory equipment-Conical connectors-Part 1：Cones and sockets YY/T 1040.1-2015 4.3		2026-07-28
		5	common requirements	Anaesthetic and respiratory equipment-Conical connectors-Part 1：Cones and sockets YY/T 1040.1-2015 5.1		2026-07-28
		6	additional requirements for 22mm conical connectors	Anaesthetic and respiratory equipment-Conical connectors-Part 1：Cones and sockets YY/T 1040.1-2015 5.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	additional requirements for 8.5mm conical connectors	Anaesthetic and respiratory equipment-Conical connectors-Part 1：Cones and sockets YY/T 1040.1-2015 5.3		2026-07-28
		8	22 mm latching connector	Anaesthetic and respiratory equipment-Conical connectors-Part 1：Cones and sockets YY/T 1040.1-2015 6		2026-07-28
61	Portable infusion devices for single use	1	All items	Portable infusion devices for single use-Non electrically driven YY 0451-2010		2026-07-28
		2	joint	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.3.2		2026-07-28
		3	filter	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.3.3		2026-07-28
		4	piping	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.3.4		2026-07-28
		5	Storage sac	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.3.5		2026-07-28
		6	Particle contamination	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.3.6		2026-07-28
		7	Sterility and Pyrogen	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.4		2026-07-28
		8	Reducing Substances	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.2		2026-07-28
		9	Metal Ions	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.3		2026-07-28
		10	PH	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.4		2026-07-28
		11	Residue on Evaporation	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.5		2026-07-28
		12	Ultraviolet Absorbance	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.6		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Ethylene Oxide Residue	Portable infusion devices for single use-Non electrically driven YY 0451-2010 4.5.7		2026-07-28
		14	Flow	Portable infusion devices for single use-Non electrically driven YY 0451-2010 5.1.1		2026-07-28
		15	Automatic liquid feeding	Portable infusion devices for single use-Non electrically driven YY 0451-2010 5.1.2		2026-07-28
62	Sterile urethral catheter for single use	1	Partial items	Sterile urethral catheter for single use YY/T 0325-2022	Except for detectability	2026-07-28
		2	biocompatibility	Sterile urethral catheter for single use YY/T 0325-2022 5.2		2026-07-28
		3	appearance	Sterile urethral catheter for single use YY/T 0325-2022 5.4		2026-07-28
		4	measurement	Sterile urethral catheter for single use YY/T 0325-2022 5.5		2026-07-28
		5	Connector	Sterile urethral catheter for single use YY/T 0325-2022 5.7		2026-07-28
		6	sterilization	Sterile urethral catheter for single use YY/T 0325-2022 5.8		2026-07-28
		7	ethylene oxide residue	Sterile urethral catheter for single use YY/T 0325-2022 5.9		2026-07-28
		8	strength	Sterile urethral catheter for single use YY/T 0325-2022 6.1		2026-07-28
		9	Connector security	Sterile urethral catheter for single use YY/T 0325-2022 6.2		2026-07-28
		10	Balloon reliability	Sterile urethral catheter for single use YY/T 0325-2022 6.3		2026-07-28
		11	Integrity of catheter inflation chamber and Volume maintenance	Sterile urethral catheter for single use YY/T 0325-2022 6.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	rate of flow	Sterile urethral catheter for single use YY/T 0325-2022 6.5		2026-07-28
		13	corrosion preventive	Sterile urethral catheter for single use YY/T 0325-2022 6.6		2026-07-28
		14	Twist stability	Sterile urethral catheter for single use YY/T 0325-2022 6.7		2026-07-28
		15	Peak tensile force	Sterile urethral catheter for single use YY/T 0325-2022 6.8		2026-07-28
		16	balloon tensile strength	Sterile urethral catheter for single use YY/T 0325-2022 6.9		2026-07-28
63	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use	1	Partial items	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008	Except for tensile yield stress, bending modulus, cantilever beam notch impact strength	2026-07-28
		2	particle appearance	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.1		2026-07-28
		3	pH	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.2		2026-07-28
		4	Heavy Metal Content	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.2		2026-07-28
		5	Cadmium Content	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.2		2026-07-28
		6	Ultraviolet Absorbance	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.2		2026-07-28
		7	Biological evaluation	Polyethylene material for manufacture of infusion, transfusion and injection equipments for medical use YY/T 0114-2008 3.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
64	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment	1	Partial items	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020	Except for aluminum and mercury	2026-07-28
		2	Water absorption rate	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.1		2026-07-28
		3	hardness	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.1		2026-07-28
		4	Tensile strength and tensile strain at break	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.1		2026-07-28
		5	180 ℃ thermal stability time	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.1		2026-07-28
		6	Low temperature impact embrittlement temperature	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.1		2026-07-28
		7	Reducing Substances in PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2026-07-28
		8	pH of PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2026-07-28
		9	Color of PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2026-07-28
		10	Ultraviolet Absorbance of PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Residue on Evaporation of PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2026-07-28
		12	zinc of PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2026-07-28
		13	Metal Ion Content in PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2026-07-28
		14	Total Heavy Metal Content in PVC Plastic Aqueous Extracts	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2026-07-28
		15	Alcoholic Extracts （DEHP） of PVC Plastic	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.2.1		2026-07-28
		16	Ash Content of PVC Plastic	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.2.2		2026-07-28
		17	Vinyl Chloride Monomer Content of PVC Plastic	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.2.2		2026-07-28
		18	Biological evaluation	Plasticized poly(vinyl chloride)compounds for transfusion(infusion) equipment GB/T 15593-2020 3.3.3		2026-07-28
65	Polypropylene material for manufacture of infusion,transfusion and injection equipments for	1	Partial items	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007	Except for tensile yield stress, bending modulus, cantilever beam notch	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	medical use				impact strength and haze	
		2	appearance	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.2		2026-07-28
		3	melt mass-flow rate	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.2		2026-07-28
		4	density	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.2		2026-07-28
		5	pH (Difference from Blank Control Liquid)	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.3		2026-07-28
		6	Heavy Metal Content	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.3		2026-07-28
		7	Cadmium Content	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.3		2026-07-28
		8	Ultraviolet Absorbance	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.3		2026-07-28
		9	Yellowing Index after Radiation	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.3		2026-07-28
		10	Biological evaluation	Polypropylene material for manufacture of infusion,transfusion and injection equipments for medical use YY/T 0242-2007 4.4		2026-07-28
66	Natural rubber latex male condoms-Requirements and test methods	1	All items	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019		2026-07-28
		2	Biological evaluation	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 6		2026-07-28
		3	Microbial limit	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 7		2026-07-28
		4	edge curl	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 9.1		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Total lubricant amount	Natural rubber latex male condoms—Requirements and test methods GB/T 7544-2019 9.2		2026-07-28
		6	size	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 9.3		2026-07-28
		7	Blasting Volum and pressure	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 10		2026-07-28
		8	Stability and storage	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 11		2026-07-28
		9	pinhole	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 12		2026-07-28
		10	Visible defects	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 13		2026-07-28
		11	integrity of individual packaging	Natural rubber latex male condoms-Requirements and test methods GB/T 7544-2019 14		2026-07-28
67	Cardiopulmonary bypass systems-Extracorporeal blood circuit	1	All items	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016		2026-07-28
		2	appearance	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.1		2026-07-28
		3	physical property	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.2		2026-07-28
		4	Biological evaluation	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.3.1		2026-07-28
		5	Sterility	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.3.2		2026-07-28
		6	Pyrogen	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.3.3		2026-07-28
		7	Residual amount of ethylene oxide	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.3.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Reducing Substances	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.1		2026-07-28
		9	Heavy Metals	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.2		2026-07-28
		10	pH	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.3		2026-07-28
		11	Residue on Evaporation	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.4		2026-07-28
		12	Ultraviolet Absorbance	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.5		2026-07-28
		13	Color	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.4.6		2026-07-28
		14	Shelf Life	Cardiopulmonary bypass systems-Extracorporeal blood circuit YY 1048-2016 4.5		2026-07-28
68	Silicone tubes and elastomeric parts for infusion and transfusion	1	All items	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008		2026-07-28
		2	appearance	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.1		2026-07-28
		3	Physical and mechanical properties of silicone rubber materials	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.2		2026-07-28
		4	Physical properties of elastic components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.3		2026-07-28
		5	Color of Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2026-07-28
		6	pH of Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Residue on Evaporation of Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2026-07-28
		8	Reducing Substances in Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2026-07-28
		9	Heavy Metal Content in Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2026-07-28
		10	Ultraviolet Absorbance of Tubing and Elastic Components	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.4		2026-07-28
		11	Biological evaluation	Silicone tubes and elastomeric parts for infusion and transfusion YY/T 0031-2008 4.5		2026-07-28
69	Dimethiconum	1	All items	ChP 2025 Vol Ⅱ		2026-07-28
70	hydroxypropyl methylcellulose	1	All items	ChP 2025 Vol Ⅳ		2026-07-28
71	Test methods for infusion, transfusion, injection equipments for medical use Part 1:	1	All items	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022		2026-07-28
		2	clarity and colour	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.1		2026-07-28
		3	reducing substance	Test methods for infusion, transfusion, injection equipments for		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	Chemical analysis methods		（oxidables）	medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.2		
		4	chloride	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.3		2026-07-28
		5	pH	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.4		2026-07-28
		6	evaporation residue	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.5		2026-07-28
		7	the total content of heavy metal ions	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.6		2026-07-28
		8	ultraviolet absorbancy degree	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.7		2026-07-28
		9	ammonium	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.8		2026-07-28
		10	partial heavy metals	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 5.9		2026-07-28
		11	analytical method of total content of heavy metal ions in material	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 6		2026-07-28
		12	analytical method of partial heavy metals in material	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 7		2026-07-28

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		№	Item/ Parameter			
		13	residue on ignition	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 8		2026-07-28
		14	determination of ethylene oxide residue-GC method	Test methods for infusion, transfusion, injection equipments for medical use Part 1: Chemical analysis methods GB/T 14233.1-2022 9		2026-07-28
72	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods	1	All items	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods GB/T 14233.2-2005		2026-07-28
		2	Sterility	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods GB/T 14233.2-2005 3		2026-07-28
		3	Bacterial endotoxins	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods GB/T 14233.2-2005 4		2026-07-28
		4	Pyrogen	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods GB/T 14233.2-2005 5		2026-07-28
		5	Acute systemic toxicity	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods GB/T 14233.2-2005 6		2026-07-28
		6	Hemolysis test	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods GB/T 14233.2-2005 7		2026-07-28
		7	Cytotoxicity	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods GB/T 14233.2-2005 8		2026-07-28
		8	Sensitization	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods GB/T 14233.2-2005 9		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Irritation	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods GB/T 14233.2-2005 10		2026-07-28
73	Conical fittings with a 6%taper for syringes, needles and certain other medical equipment	1	Implantation test	Test methods for infusion, transfusion, injection equipment for medical use-Part 2：Biological test methods GB/T 14233.2-2005 11		2026-07-28
		2	size	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part1：General requirement GB/T 1962.1-2015 4.1		2026-07-28
		3	Liquid leakage	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part1：General requirement GB/T 1962.1-2015 4.2		2026-07-28
		4	Air leak	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part1：General requirement GB/T 1962.1-2015 4.3		2026-07-28
		5	separating force	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part1：General requirement GB/T 1962.1-2015 4.4		2026-07-28
		6	stress cracks	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part1：General requirement GB/T 1962.1-2015 4.5		2026-07-28
		7	All items	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part2：Lock fittings GB/T 1962.2-2001		2026-07-28
		8	size	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part2：Lock fittings GB/T 1962.2-2001 4.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Liquid leakage	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part2：Lock fittings GB/T 1962.2-2001 4.2.1		2026-07-28
		10	Air leak	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part2：Lock fittings GB/T 1962.2-2001 4.2.2		2026-07-28
		11	separating force	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part2：Lock fittings GB/T 1962.2-2001 4.3		2026-07-28
		12	Unscrew torque	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part2：Lock fittings GB/T 1962.2-2001 4.4		2026-07-28
		13	Ease of assembly	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part2：Lock fittings GB/T 1962.2-2001 4.5		2026-07-28
		14	overload resistance	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part2：Lock fittings GB/T 1962.2-2001 4.6		2026-07-28
		15	stress cracks	Conical fittings with a 6%（Luer）taper for syringes, needles and certain other medical equipment-Part2：Lock fittings GB/T 1962.2-2001 4.7		2026-07-28
74	Medical absorbent cotton	1	All items	Medical absorbent cotton YY/T 0330-2015		2026-07-28
		2	character	Medical absorbent cotton YY/T 0330-2015 3.1		2026-07-28
		3	Identification	Medical absorbent cotton YY/T 0330-2015 3.2		2026-07-28
		4	foreign fiber	Medical absorbent cotton YY/T 0330-2015 3.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	nep	Medical absorbent cotton YY/T 0330-2015 3.4		2026-07-28
		6	Solubles in Water	Medical absorbent cotton YY/T 0330-2015 3.5		2026-07-28
		7	pH	Medical absorbent cotton YY/T 0330-2015 3.6		2026-07-28
		8	Sedimentation Time	Medical absorbent cotton YY/T 0330-2015 3.7		2026-07-28
		9	Water Absorption	Medical absorbent cotton YY/T 0330-2015 3.8		2026-07-28
		10	Solubles in Ether	Medical absorbent cotton YY/T 0330-2015 3.9		2026-07-28
		11	Fluorescent Substances	Medical absorbent cotton YY/T 0330-2015 3.10		2026-07-28
		12	Loss on Drying	Medical absorbent cotton YY/T 0330-2015 3.11		2026-07-28
		13	Sulfated Ash	Medical absorbent cotton YY/T 0330-2015 3.12		2026-07-28
		14	Surface Active Substances	Medical absorbent cotton YY/T 0330-2015 3.13		2026-07-28
		15	Extractable Colorants	Medical absorbent cotton YY/T 0330-2015 3.14		2026-07-28
		16	Ethylene Oxide Residue	Medical absorbent cotton YY/T 0330-2015 3.15		2026-07-28
		17	Microbial limit	Medical absorbent cotton YY/T 0330-2015 3.16		2026-07-28
75	Medical absorbent gauze	1	All items	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006		2026-07-28
		2	Liquid Permeability	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 3.3	Only used when cited or	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					requested by a customer	
		3	Fiber Identification	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.1	Only used when cited or requested by a customer	2026-07-28
		4	pH	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.2	Only used when cited or requested by a customer	2026-07-28
		5	Foreign Fibers	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.3	Only used when cited or requested by a customer	2026-07-28
		6	Fluorescent Substances	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.4	Only used when cited or requested by a customer	2026-07-28
		7	number of threads	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.5	Only used when cited or	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					requested by a customer	
		8	Mass per square meter	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.6	Only used when cited or requested by a customer	2026-07-28
		9	Minimum breaking force	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.7	Only used when cited or requested by a customer	2026-07-28
		10	Sinking time	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.8	Only used when cited or requested by a customer	2026-07-28
		11	Solubles in Ether	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.9	Only used when cited or requested by a customer	2026-07-28
		12	Surface Active Substances	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.10	Only used when cited or	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					requested by a customer	
		13	Solubles in Water	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.11	Only used when cited or requested by a customer	2026-07-28
		14	Starch and Dextrin	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.12	Only used when cited or requested by a customer	2026-07-28
		15	Extractable Colorants	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.13	Only used when cited or requested by a customer	2026-07-28
		16	Loss on Drying	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.14	Only used when cited or requested by a customer	2026-07-28
		17	Sulfated Ash	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze YY 0331-2006 4.15	Only used when cited or	2026-07-28

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		№	Item/ Parameter			
					requested by a customer	
76	Primary wound dressing	1	All items	Primary wound dressing YY/T 0471.1~6-2004	Use only when quoted or requested by the customer	2026-07-28
		2	free swell absorptive capacity	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.2		2026-07-28
		3	fluid handling capacity	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.3		2026-07-28
		4	Liquid Affinity of Amorphous Hydrogels	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.4		2026-07-28
		5	Gelling Properties	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.5		2026-07-28
		6	Dispersion Characteristics	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.6		2026-07-28
		7	Dispersion/Solubility of Hydrogel Additives	Test methods for primary wound dressing—Part 1:Aspects of absorbency YY/T 0471.1-2004 3.7		2026-07-28
		8	Test method for moisture vapor transmission rate	Test methods for primary wound dressings-Part 2：Moisture vapour transmission rate of permeable film dressings YY/T 0471.2-2004 3		2026-07-28
		9	Test method for waterproofness	Test methods for primary wound dressings-Part 3: Waterproofness YY/T 0471.3-2004 3.2		2026-07-28
		10	Comfort test method	Test methods for primary wound dressing-Part 4:Conformability YY/T 0471.4-2004 3.2		2026-07-28

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		11	Bacterial barrier properties	Test methods for primary wound dressing-Part 5:Bacterial barrier properties YY/T 0471.5-2004 3		2026-07-28
		12	Odor Transmission Test	Test methods for primary wound dressings-Part 6:Odour control YY/T 0471.6-2004 3		2026-07-28
77	Medical suture needle (without thread)	1	All items	Medical suture needle YY/T 0043-2016		2026-07-28
		2	appearance	Medical suture needle YY/T 0043-2016 4.1		2026-07-28
		3	Hardness	Medical suture needle YY/T 0043-2016 4.2.1		2026-07-28
		4	elasticity	Medical suture needle YY/T 0043-2016 4.2.2		2026-07-28
		5	toughness	Medical suture needle YY/T 0043-2016 4.2.3		2026-07-28
		6	Needle tip strength	Medical suture needle YY/T 0043-2016 4.2.4		2026-07-28
		7	Piercing force	Medical suture needle YY/T 0043-2016 4.3.1		2026-07-28
		8	cutting force	Medical suture needle YY/T 0043-2016 4.3.2		2026-07-28
		9	Initial contamination bacteria	Medical suture needle YY/T 0043-2016 4.4		2026-07-28
		10	corrosion resistance	Medical suture needle YY/T 0043-2016 4.5		2026-07-28
		11	Sterility	Medical suture needle YY/T 0043-2016 4.6		2026-07-28
		12	Ethylene Oxide Residue	Medical suture needle YY/T 0043-2016 4.7		2026-07-28
		13	Cytotoxicity	Medical suture needle YY/T 0043-2016 4.8.1		2026-07-28

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		14	Sensitization	Medical suture needle YY/T 0043-2016 4.8.2		2026-07-28
		15	Irritation	Medical suture needle YY/T 0043-2016 4.8.3		2026-07-28
78	Non-absorbable surgical suture	1	All items	Non-absorbable surgical suture YY 0167-2020		2026-07-28
		2	appearance	Non-absorbable surgical suture YY 0167-2020 4.1		2026-07-28
		3	Wire diameter	Non-absorbable surgical suture YY 0167-2020 4.2		2026-07-28
		4	breaking strength	Non-absorbable surgical suture YY 0167-2020 4.3		2026-07-28
		5	Needle and thread connection strength	Non-absorbable surgical suture YY 0167-2020 4.4		2026-07-28
		6	fade	Non-absorbable surgical suture YY 0167-2020 4.5		2026-07-28
		7	length	Non-absorbable surgical suture YY 0167-2020 4.6		2026-07-28
		8	Sterility	Non-absorbable surgical suture YY 0167-2020 4.7		2026-07-28
		9	Ethylene Oxide Residue	Non-absorbable surgical suture YY 0167-2020 4.8		2026-07-28
		10	Biological evaluation	Non-absorbable surgical suture YY 0167-2020 4.9		2026-07-28
		11	identification	Non-absorbable surgical suture YY 0167-2020 4.10		2026-07-28
79	Absorbable surgical suture	1	All items	Absorbable surgical suture YY 1116-2020		2026-07-28
		2	appearance	Absorbable surgical suture YY 1116-2020 4.1		2026-07-28
		3	Wire diameter	Absorbable surgical suture YY 1116-2020 4.2		2026-07-28

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		№	Item/ Parameter			
		4	breaking strength	Absorbable surgical suture YY 1116-2020 4.3		2026-07-28
		5	Needle and thread connection strength	Absorbable surgical suture YY 1116-2020 4.4		2026-07-28
		6	length	Absorbable surgical suture YY 1116-2020 4.5		2026-07-28
		7	Soluble Chromium Compounds	Absorbable surgical suture YY 1116-2020 4.6.1		2026-07-28
		8	Heavy Metals	Absorbable surgical suture YY 1116-2020 4.6.2		2026-07-28
		9	Moisture Content	Absorbable surgical suture YY 1116-2020 4.6.3		2026-07-28
		10	Fade	Absorbable surgical suture YY 1116-2020 4.6.4		2026-07-28
		11	Ethylene Oxide Residue	Absorbable surgical suture YY 1116-2020 4.6.5		2026-07-28
		12	Sterility	Absorbable surgical suture YY 1116-2020 4.7		2026-07-28
		13	Biological evaluation	Absorbable surgical suture YY 1116-2020 4.8		2026-07-28
		14	identification	Absorbable surgical suture YY 1116-2020 4.9		2026-07-28
80	General specifications for stapler	1	All items	General specifications for stapler YY/T 0245-2008		2026-07-28
		2	Materials for Suture Needles	General specifications for stapler YY/T 0245-2008 4.1		2026-07-28
		3	Usage performance	General specifications for stapler YY/T 0245-2008 4.2		2026-07-28
		4	hardness	General specifications for stapler YY/T 0245-2008 4.3		2026-07-28
		5	Surface roughness	General specifications for stapler YY/T 0245-2008 4.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Corrosion Resistance	General specifications for stapler YY/T 0245-2008 4.5		2026-07-28
		7	Peel strength of packaging sealing	General specifications for stapler YY/T 0245-2008 4.6		2026-07-28
		8	appearance	General specifications for stapler YY/T 0245-2008 4.7		2026-07-28
		9	size	General specifications for stapler YY/T 0245-2008 4.8		2026-07-28
		10	Sterility	General specifications for stapler YY/T 0245-2008 4.9.1		2026-07-28
		11	Ethylene Oxide Residue	General specifications for stapler YY/T 0245-2008 4.9.2		2026-07-28
		12	Cytotoxicity	General specifications for stapler YY/T 0245-2008 4.10.1		2026-07-28
		13	Sensitization	General specifications for stapler YY/T 0245-2008 4.10.2		2026-07-28
		14	Irritation	General specifications for stapler YY/T 0245-2008 4.10.3		2026-07-28
81	Single-use puncture set local anaesthesia	1	Partial items	Single-use puncture set local anaesthesia YY/T0321.1-2022	Except for radiopacity	2026-07-28
		2	Single-use needle for anaesthesia	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.1		2026-07-28
		3	Single-use filter for anaesthesia	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.2		2026-07-28
		4	Basic dimensions	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.1		2026-07-28
		5	Lateral aperture	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.3		2026-07-28
		6	Tick Labelings	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.4		2026-07-28
		7	Flow	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Breaking force	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.6		2026-07-28
		9	Joint	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.7		2026-07-28
		10	Particle contamination	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.8		2026-07-28
		11	Connection firmness	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.9		2026-07-28
		12	Tightness	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.10		2026-07-28
		13	Bending resistance	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.11		2026-07-28
		14	Corrosion resistance of steel wire	Single-use puncture set local anaesthesia YY/T0321.1-2022 5.3.12		2026-07-28
		15	reducing substance（oxidables）	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.2		2026-07-28
		16	metal ions	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.3		2026-07-28
		17	pH	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.4		2026-07-28
		18	evaporation residue	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.5		2026-07-28
		19	ultraviolet absorbancy degree	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.6		2026-07-28
		20	ethylene oxide residue	Single-use puncture set local anaesthesia YY/T0321.1-2022 6.7		2026-07-28
		21	sterility	Single-use puncture set local anaesthesia YY/T0321.1-2022 7.2		2026-07-28
		22	bacterial endotoxin	Single-use puncture set local anaesthesia YY/T0321.1-2022 7.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
82	Single-use needle for anaesthesia	1	All items	Single-use needle for anaesthesia YY/T 0321.2-2021		2026-07-28
		2	Basic dimensions	Single-use needle for anaesthesia YY/T 0321.2-2021 5.1		2026-07-28
		3	Needle tube and needle core seat	Single-use needle for anaesthesia YY/T 0321.2-2021 5.2		2026-07-28
		4	Needle tube	Single-use needle for anaesthesia YY/T 0321.2-2021 5.3		2026-07-28
		5	Lining core	Single-use needle for anaesthesia YY/T 0321.2-2021 5.4		2026-07-28
		6	Needle tip	Single-use needle for anaesthesia YY/T 0321.2-2021 5.5		2026-07-28
		7	Flow	Single-use needle for anaesthesia YY/T 0321.2-2021 5.6		2026-07-28
		8	Connection firmness	Single-use needle for anaesthesia YY/T 0321.2-2021 5.7		2026-07-28
		9	Connection integrity	Single-use needle for anaesthesia YY/T 0321.2-2021 5.8		2026-07-28
		10	Particle contamination	Single-use needle for anaesthesia YY/T 0321.2-2021 5.9		2026-07-28
		11	Color code	Single-use needle for anaesthesia YY/T 0321.2-2021 5.1		2026-07-28
		12	metal ions	Single-use needle for anaesthesia YY/T 0321.2-2021 6.2		2026-07-28
		13	pH	Single-use needle for anaesthesia YY/T 0321.2-2021 6.3		2026-07-28
		14	ethylene oxide residue	Single-use needle for anaesthesia YY/T 0321.2-2021 6.4		2026-07-28
		15	sterility	Single-use needle for anaesthesia YY/T 0321.2-2021 7.2		2026-07-28
		16	bacterial endotoxin	Single-use needle for anaesthesia YY/T 0321.2-2021 7.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
83	Single-use filter for anaesthesia	1	All items	Single-use filter for anaesthesia YY/T 0321.3-2022		2026-07-28
		2	Joint	Single-use filter for anaesthesia YY/T 0321.3-2022 5.2		2026-07-28
		3	Filtering performance requirements	Single-use filter for anaesthesia YY/T 0321.3-2022 5.3		2026-07-28
		4	Tightness	Single-use filter for anaesthesia YY/T 0321.3-2022 5.4		2026-07-28
		5	Particle contamination	Single-use filter for anaesthesia YY/T 0321.3-2022 5.5		2026-07-28
		6	Fluid flow	Single-use filter for anaesthesia YY/T 0321.3-2022 5.6		2026-07-28
		7	reducing substance （oxidables）	Single-use filter for anaesthesia YY/T 0321.3-2022 6.2		2026-07-28
		8	metal ions	Single-use filter for anaesthesia YY/T 0321.3-2022 6.3		2026-07-28
		9	pH	Single-use filter for anaesthesia YY/T 0321.3-2022 6.4		2026-07-28
		10	ethylene oxide residue	Single-use filter for anaesthesia YY/T 0321.3-2022 6.5		2026-07-28
		11	sterility	Single-use filter for anaesthesia YY/T 0321.3-2022 7.2		2026-07-28
		12	bacterial endotoxin	Single-use filter for anaesthesia YY/T 0321.3-2022 7.3		2026-07-28
84	Intravenous needles for single use	1	All items	Intravenous needles for single use GB 18671-2009		2026-07-28
		2	Materials	Intravenous needles for single use GB 18671-2009 5		2026-07-28
		3	Color code	Intravenous needles for single use GB 18671-2009 6.1		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Particle contamination	Intravenous needles for single use GB 18671-2009 6.2		2026-07-28
		5	Connection firmness	Intravenous needles for single use GB 18671-2009 6.3		2026-07-28
		6	leakage	Intravenous needles for single use GB 18671-2009 6.4		2026-07-28
		7	Flow	Intravenous needles for single use GB 18671-2009 6.5		2026-07-28
		8	Needle length	Intravenous needles for single use GB 18671-2009 6.6		2026-07-28
		9	Needle tip	Intravenous needles for single use GB 18671-2009 6.7		2026-07-28
		10	lubricant	Intravenous needles for single use GB 18671-2009 6.8		2026-07-28
		11	Pin seat connection	Intravenous needles for single use GB 18671-2009 6.9		2026-07-28
		12	needle handle	Intravenous needles for single use GB 18671-2009 6.10		2026-07-28
		13	flexible pipe	Intravenous needles for single use GB 18671-2009 6.11		2026-07-28
		14	protective sheath and cap	Intravenous needles for single use GB 18671-2009 6.12		2026-07-28
		15	Reducing Substances	Intravenous needles for single use GB 18671-2009 7.1		2026-07-28
		16	Metal Ions	Intravenous needles for single use GB 18671-2009 7.2		2026-07-28
		17	Acid-Base Titration	Intravenous needles for single use GB 18671-2009 7.3		2026-07-28
		18	Residue on Evaporation	Intravenous needles for single use GB 18671-2009 7.4		2026-07-28
		19	Ultraviolet Absorbance	Intravenous needles for single use GB 18671-2009 7.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		20	Biological evaluation	Intravenous needles for single use GB 18671-2009 8.1		2026-07-28
		21	Sterility	Intravenous needles for single use GB 18671-2009 8.2		2026-07-28
		22	Bacterial endotoxins	Intravenous needles for single use GB 18671-2009 8.3		2026-07-28
85	Sterile hypodermic needles for single use	1	All items	Sterile hypodermic needles for single use GB 15811- 2016		2026-07-28
		2	cleaning	Sterile hypodermic needles for single use GB 15811- 2016 6.1		2026-07-28
		3	Color code	Sterile hypodermic needles for single use GB 15811- 2016 6.2		2026-07-28
		4	honest	Sterile hypodermic needles for single use GB 15811- 2016 6.3		2026-07-28
		5	Connection firmness	Sterile hypodermic needles for single use GB 15811- 2016 6.4		2026-07-28
		6	patency	Sterile hypodermic needles for single use GB 15811- 2016 6.5		2026-07-28
		7	Needle holder and sheath fit	Sterile hypodermic needles for single use GB 15811- 2016 6.6		2026-07-28
		8	Needle tip	Sterile hypodermic needles for single use GB 15811- 2016 6.7		2026-07-28
		9	Needle tube	Sterile hypodermic needles for single use GB 15811- 2016 6.8		2026-07-28
		10	Needle holder	Sterile hypodermic needles for single use GB 15811- 2016 6.9		2026-07-28
		11	pH	Sterile hypodermic needles for single use GB 15811- 2016 7.2		2026-07-28
		12	Total Heavy Metal Content (Metal Ions)	Sterile hypodermic needles for single use GB 15811- 2016 7.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Sterility	Sterile hypodermic needles for single use GB 15811- 2016 8.2		2026-07-28
		14	Bacterial endotoxins	Sterile hypodermic needles for single use GB 15811- 2016 8.3		2026-07-28
		15	Hemolysis test	Sterile hypodermic needles for single use GB 15811- 2016 8.4		2026-07-28
		16	Biological evaluation	Sterile hypodermic needles for single use GB 15811- 2016 8.5		2026-07-28
86	Sterile syringes for single use	1	All items	Sterile syringes for single use GB 15810-2019		2026-07-28
		2	appearance	Sterile syringes for single use GB 15810-2019 5.1		2026-07-28
		3	Scale capacity tolerance	Sterile syringes for single use GB 15810-2019 5.2		2026-07-28
		4	Graduated scale	Sterile syringes for single use GB 15810-2019 5.3		2026-07-28
		5	overcoat	Sterile syringes for single use GB 15810-2019 5.4		2026-07-28
		6	Hand spacing	Sterile syringes for single use GB 15810-2019 5.5.1		2026-07-28
		7	Matching between piston and core rod	Sterile syringes for single use GB 15810-2019 5.5.2		2026-07-28
		8	cone tip	Sterile syringes for single use GB 15810-2019 5.6		2026-07-28
		9	residual capacity	Sterile syringes for single use GB 15810-2019 5.7.1		2026-07-28
		10	Body tightness	Sterile syringes for single use GB 15810-2019 5.7.2		2026-07-28
		11	Sliding performance	Sterile syringes for single use GB 15810-2019 5.7.3		2026-07-28
		12	Matching of outer sleeve and piston	Sterile syringes for single use GB 15810-2019 5.7.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			component			
		13	pH	Sterile syringes for single use GB 15810-2019 6.1		2026-07-28
		14	Extractable Metal Content	Sterile syringes for single use GB 15810-2019 6.2		2026-07-28
		15	readily oxidation substance	Sterile syringes for single use GB 15810-2019 6.3		2026-07-28
		16	Ethylene Oxide Residue	Sterile syringes for single use GB 15810-2019 6.4		2026-07-28
		17	Sterility	Sterile syringes for single use GB 15810-2019 7.2		2026-07-28
		18	Bacterial endotoxins	Sterile syringes for single use GB 15810-2019 7.3		2026-07-28
87	syringe needle	1	All items	Syringe needle YY/T 0282-2009	Only used when cited or requested by a customer	2026-07-28
		2	Needle holder	Syringe needle YY/T 0282-2009 5.1	Only used when cited or requested by a customer	2026-07-28
		3	Needle tube	Syringe needle YY/T 0282-2009 5.2	Only used when cited or requested by a	2026-07-28

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		№	Item/ Parameter			
					customer	
		4	Needle tip	Syringe needle YY/T 0282-2009 5.3	Only used when cited or requested by a customer	2026-07-28
		5	connectivity	Syringe needle YY/T 0282-2009 5.4	Only used when cited or requested by a customer	2026-07-28
		6	patency	Syringe needle YY/T 0282-2009 5.5	Only used when cited or requested by a customer	2026-07-28
88	Hydroxyapatite powder for medical applications	1	All items	Hydroxyapatite powder for medical applications YY 0303-1998	Use only when quoted or requested by the customer	2026-07-28
		2	appearance	Hydroxyapatite powder for medical applications YY 0303-1998 4.2	Use only when quoted or requested by the	2026-07-28

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		№	Item/ Parameter			
					customer	
		3	granularity	Hydroxyapatite powder for medical applications YY 0303-1998 4.3	Use only when quoted or requested by the customer	2026-07-28
		4	Hydroxyapatite Content	Hydroxyapatite powder for medical applications YY 0303-1998 4.4	Use only when quoted or requested by the customer	2026-07-28
		5	Calcium to Phosphorus Atomic Ratio	Hydroxyapatite powder for medical applications YY 0303-1998 4.5	Use only when quoted or requested by the customer	2026-07-28
		6	Infrared Absorption Spectra	Hydroxyapatite powder for medical applications YY 0303-1998 4.6	Use only when quoted or requested by the customer	2026-07-28
		7	Limits for Impurity and Heavy Metal Elements	Hydroxyapatite powder for medical applications YY 0303-1998 4.7	Use only when quoted or requested by the	2026-07-28

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		№	Item/ Parameter			
					customer	
89	Plasma sprayed hydroxyapatite coated - titanium dental implant	1	All items	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304－2009		2026-07-28
		2	appearance	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304－2009 4.3.1		2026-07-28
		3	Chemical Composition of HA Coating	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304－2009 4.3.2.1		2026-07-28
		4	Chemical Composition and Microstructure of Titanium and Titanium Alloy Materials	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304－2009 4.3.2.2		2026-07-28
		5	Tensile bonding strength between HA coating and titanium substrate	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304－2009 4.3.3		2026-07-28
		6	Dynamic fatigue test	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304－2009 4.3.4		2026-07-28
		7	Biological evaluation	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304－2009 4.4		2026-07-28
		8	Sterility	Plasma sprayed hydroxyapatite coated - titanium dental implant YY 0304－2009 4.5		2026-07-28
90	Wrought titanium and titanium dental	1	All items	Wrought titanium and titanium dental implant YY 0315-2016		2026-07-28
		2	Chemical Properties	Wrought titanium and titanium dental implant YY 0315-2016 5.1		2026-07-28

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		№	Item/ Parameter			
	implant	3	Microstructure	Wrought titanium and titanium dental implant YY 0315-2016 5.2		2026-07-28
		4	size	Wrought titanium and titanium dental implant YY 0315-2016 5.3		2026-07-28
		5	appearance	Wrought titanium and titanium dental implant YY 0315-2016 5.4.1		2026-07-28
		6	Surface defects	Wrought titanium and titanium dental implant YY 0315-2016 5.4.2		2026-07-28
		7	roughness	Wrought titanium and titanium dental implant YY 0315-2016 5.4.3		2026-07-28
		8	cleaning	Wrought titanium and titanium dental implant YY 0315-2016 5.5		2026-07-28
		9	Torsional resistance performance	Wrought titanium and titanium dental implant YY 0315-2016 5.6.1		2026-07-28
		10	Tightening torque	Wrought titanium and titanium dental implant YY 0315-2016 5.6.2		2026-07-28
		11	Fatigue limit	Wrought titanium and titanium dental implant YY 0315-2016 5.6.3		2026-07-28
		12	Sterility	Wrought titanium and titanium dental implant YY 0315-2016 5.7		2026-07-28
		13	Bacterial endotoxins	Wrought titanium and titanium dental implant YY 0315-2016 5.8		2026-07-28
		14	Biological evaluation	Wrought titanium and titanium dental implant YY 0315-2016 5.9		2026-07-28
91	Dental-Orthodontic bracket adhesive materials	1	All items	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009		2026-07-28
		2	appearance	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.1		2026-07-28
		3	working hours	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Curing Time	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.3		2026-07-28
		5	Sensitivity of materials to environmental light	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.4		2026-07-28
		6	Adhesive Strength	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.5		2026-07-28
		7	Biological evaluation	Dental-Orthodontic bracket adhesive materials YY/T 0269-2009 4.6		2026-07-28
92	Dental-Ceramic	1	Partial items	Dental-Ceramic YY 0716-2009	Except for linear expansion coefficient	2026-07-28
		2	uniformity	Dental-Ceramic YY 0716-2009 5.1		2026-07-28
		3	No foreign objects	Dental-Ceramic YY 0716-2009 5.2		2026-07-28
		4	Mixing and compaction properties of Type I ceramics	Dental-Ceramic YY 0716-2009 5.3		2026-07-28
		5	Flexural Strength	Dental-Ceramic YY 0716-2009 5.4.1		2026-07-28
		6	Chemical Solubility	Dental-Ceramic YY 0716-2009 5.4.2		2026-07-28
		7	glass transition temperature	Dental-Ceramic YY 0716-2009 5.4.4		2026-07-28
		8	Biological evaluation	Dental-Ceramic YY 0716-2009 5.5		2026-07-28
93	Artificial teeth for dental	1	All items	Dentistry-Artificial teeth for dental prostheses YY 0300-2009	Except for radioactive	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	prostheses	2	Biological evaluation	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.1.1		2026-07-28
		3	size	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.1.2		2026-07-28
		4	Color and fusion	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.1.3		2026-07-28
		5	Surface finish	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.1.4		2026-07-28
		6	Pores and other defects	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.1.5		2026-07-28
		7	Retaining groove	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.2.2		2026-07-28
		8	heat resistance	Dentistry-Artificial teeth for dental prostheses YY 0300-2009 5.2.3		2026-07-28
94	Biological evaluation of medical devices used in dentistry	1	Test method-Acute oral toxicity test	Biological evaluation of medical devices used in dentistry-Part2:Test method-Acute oral toxicity test YY/T 0127.14-2009		2026-07-28
		2	Subacute and subchronic systemic toxicity test:oral route	Biological evaluation of medical devices used in dentistry-Part15:Subacute and subchronic systemic toxicity test:oral route YY/T 0127.15-2018		2026-07-28
		3	Mouse lymphoma cells (TK) gene mutation test	Biological evaluation of medical devices used in dentistry-Part17:Mouse lymphoma cells (TK) gene mutation test YY/T 0127.17-2014		2026-07-28
		4	Micronucleus test	Dentistry-Biological evaluation of medical devices used in dentistry Part 2:Test method-Micronucleus test YY/T 0127.12-2008		2026-07-28
		5	Oral mucous irritation test	Biological evaluation of medical devices used in dentistry Part 13:Oral mucous irritation test YY/T 0127.13-2018		2026-07-28
		6	Hemolysis test	Biological testing methods for oral materials Hemolysis test YY/T 0127.1-93		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Acute systemic toxicity : intravenous path	Biological evaluation of medical devices used in dentistry-Part 2: Test method—Acute systemic toxicity : intravenous path YY/T 0127.2-2009		2026-07-28
		8	Subcutaneous implant test	Biological evaluation of dental materials— Part2: Biological evaluation test method of dental materials-Subcutaneous implant test YY/T 0127.8-2001		2026-07-28
		9	Salmonella typhimurium reverse mutation assay(Ames mutagenicity test)	Biological evaluation of medical devices used in dentistry— Part 2:Test method-Salmonella typhimurium reverse mutation assay(Ames mutagenicity test) YY/T 0127.10-2009		2026-07-28
95	Dental elevators	1	All items	Dental elevators YY/T 0170-2011		2026-07-28
		2	size	Dental elevators YY/T 0170-2011 4.1		2026-07-28
		3	hardness	Dental elevators YY/T 0170-2011 4.2		2026-07-28
		4	tension	Dental elevators YY/T 0170-2011 4.3.1		2026-07-28
		5	torque	Dental elevators YY/T 0170-2011 4.3.2		2026-07-28
		6	Surface roughness	Dental elevators YY/T 0170-2011 4.4		2026-07-28
		7	Corrosion Resistance	Dental elevators YY/T 0170-2011 4.5		2026-07-28
		8	Pressure resistant steam performance	Dental elevators YY/T 0170-2011 4.6		2026-07-28
		9	heat resistance	Dental elevators YY/T 0170-2011 4.7		2026-07-28
		10	Leakage resistance performance	Dental elevators YY/T 0170-2011 4.8		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	appearance	Dental elevators YY/T 0170-2011 4.9		2026-07-28
96	Dental scalers	1	All items	Dental scalers YY/T 0274-2011		2026-07-28
		2	size	Dental scalers YY/T 0274-2011 4.1		2026-07-28
		3	hardness	Dental scalers YY/T 0274-2011 4.2		2026-07-28
		4	sharpness	Dental scalers YY/T 0274-2011 4.3		2026-07-28
		5	tension	Dental scalers YY/T 0274-2011 4.4.1		2026-07-28
		6	torque	Dental scalers YY/T 0274-2011 4.4.2		2026-07-28
		7	Surface roughness	Dental scalers YY/T 0274-2011 4.5		2026-07-28
		8	Corrosion Resistance	Dental-scalers YY/T 0274-2011 4.6		2026-07-28
		9	heat resistance	Dental scalers YY/T 0274-2011 4.7		2026-07-28
		10	appearance	Dental scalers YY/T 0274-2011 4.8		2026-07-28
97	Apical elevators	1	All items	Apical elevators YY/T 0277-1995		2026-07-28
		2	size	Apical elevators YY/T 0277-1995 4.1		2026-07-28
		3	material	Apical elevators YY/T 0277-1995 4.2		2026-07-28
		4	hardness	Apical elevators YY/T 0277-1995 4.3		2026-07-28
		5	Corrosion Resistance	Apical elevators YY/T 0277-1995 4.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Surface roughness	Apical elevators YY/T 0277-1995 4.5		2026-07-28
		7	cutting edge	Apical elevators YY/T 0277-1995 4.6		2026-07-28
		8	Head strength	Apical elevators YY/T 0277-1995 4.7		2026-07-28
		9	weld	Apical elevators YY/T 0277-1995 4.8		2026-07-28
98	Dental pluggers	1	All items	Dental pluggers YY/T 0275-2011		2026-07-28
		2	size	Dental pluggers YY/T 0275-2011 4.1		2026-07-28
		3	hardness	Dental pluggers YY/T 0275-2011 4.2		2026-07-28
		4	toughness	Dental pluggers YY/T 0275-2011 4.3		2026-07-28
		5	Connection firmness	Dental pluggers YY/T 0275-2011 4.4		2026-07-28
		6	Surface roughness	Dental pluggers YY/T 0275-2011 4.5		2026-07-28
		7	Corrosion Resistance	Dental pluggers YY/T0275-2011 4.6		2026-07-28
		8	appearance	Dental pluggers YY/T 0275-2011 4.7		2026-07-28
99	Dental elevators	1	All items	Dental elevators YY/T 0170-2011		2026-07-28
		2	size	Dental elevators YY/T 0170-2011 4.1		2026-07-28
		3	hardness	Dental elevators YY/T 0170-2011 4.2		2026-07-28
		4	tension	Dental elevators YY/T 0170-2011 4.3.1		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	torque	Dental elevators YY/T 0170-2011 4.3.2		2026-07-28
		6	Surface roughness	Dental elevators YY/T 0170-2011 4.4		2026-07-28
		7	Corrosion Resistance	Dental elevators YY/T 0170-2011 4.5		2026-07-28
		8	Pressure resistant steam performance	Dental elevators YY/T 0170-2011 4.6		2026-07-28
		9	heat resistance	Dental elevators YY/T 0170-2011 4.7		2026-07-28
		10	Leakage resistance performance	Dental elevators YY/T 0170-2011 4.8		2026-07-28
		11	appearance	Dental elevators YY/T 0170-2011 4.9		2026-07-28
100	Plasmapheresis centrifuge apparatus for single use	1	Partial items	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017	Except for microbial impermeability	2026-07-28
		2	plasmapheresis centrifuge	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 5.1		2026-07-28
		3	plasma pipeline	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 5.2		2026-07-28
		4	plasma bag	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 5.3		2026-07-28
		5	Reducing Substances	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.1		2026-07-28
		6	Metal Ions	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.2		2026-07-28
		7	PH	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Residue on Evaporation	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.4		2026-07-28
		9	Ultraviolet Absorbance	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.5		2026-07-28
		10	Ethylene Oxide Residue	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.1.6		2026-07-28
		11	Reducing Substances	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.1		2026-07-28
		12	Metal Ions	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.2		2026-07-28
		13	PH	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.3		2026-07-28
		14	Residue on Evaporation	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.4		2026-07-28
		15	Ultraviolet Absorbance	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.5		2026-07-28
		16	Ethylene Oxide Residue	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.2.6		2026-07-28
		17	Ethylene Oxide Residue	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 6.3.2		2026-07-28
		18	Biological evaluation	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.1.1		2026-07-28
		19	Sterility	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.1.2		2026-07-28
		20	Biological evaluation	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.2.1		2026-07-28
		21	Sterility	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.2.2		2026-07-28
		22	Plasma bag	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		23	Bacterial endotoxins	Plasmapheresis centrifuge apparatus for single use YY/T 0326-2017 7.4		2026-07-28
101	Leukocyte reduction filters for single use	1	All items	Leukocyte reduction filters for single use YY 0329-2009		2026-07-28
		2	appearance	Leukocyte reduction filters for single use YY 0329-2009 5.1.1		2026-07-28
		3	tightness	Leukocyte reduction filters for single use YY 0329-2009 5.1.2		2026-07-28
		4	connection firmness	Leukocyte reduction filters for single use YY 0329-2009 5.1.3		2026-07-28
		5	particle	Leukocyte reduction filters for single use YY 0329-2009 5.1.4		2026-07-28
		6	flow	Leukocyte reduction filters for single use YY 0329-2009 5.1.5		2026-07-28
		7	protective sheath	Leukocyte reduction filters for single use YY 0329-2009 5.1.6		2026-07-28
		8	Reducing Substances (Easily Oxidizable Substances)	Leukocyte reduction filters for single use YY 0329-2009 5.2.1		2026-07-28
		9	Metal Ions	Leukocyte reduction filters for single use YY 0329-2009 5.2.2		2026-07-28
		10	PH	Leukocyte reduction filters for single use YY 0329-2009 5.2.3		2026-07-28
		11	Residue on Evaporation	Leukocyte reduction filters for single use YY 0329-2009 5.2.4		2026-07-28
		12	Ultraviolet Absorbance	Leukocyte reduction filters for single use YY 0329-2009 5.2.5		2026-07-28
		13	Ethylene Oxide Residue	Leukocyte reduction filters for single use YY 0329-2009 5.2.6		2026-07-28
		14	Sterility	Leukocyte reduction filters for single use YY 0329-2009 5.3.1		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Bacterial endotoxins	Leukocyte reduction filters for single use YY 0329-2009 5.3.2		2026-07-28
		16	Biological evaluation	Leukocyte reduction filters for single use YY 0329-2009 5.5		2026-07-28
102	Disposable hemoperfutor	1	All items	Disposable hemoperfutor YY/T 0464-2019		2026-07-28
		2	appearance	Disposable hemoperfutor YY/T 0464-2019 5.1		2026-07-28
		3	connection between blood inlet and outlet and pipeline	Disposable hemoperfutor YY/T 0464-2019 5.2		2026-07-28
		4	filling adsorbent content	Disposable hemoperfutor YY/T 0464-2019 5.3		2026-07-28
		5	blood volume	Disposable hemoperfutor YY/T 0464-2019 5.4		2026-07-28
		6	particle shedding	Disposable hemoperfutor YY/T 0464-2019 5.5		2026-07-28
		7	Reducing Substances (Easily Oxidizable Substances)	Disposable hemoperfutor YY/T0464-2019 5.6.1		2026-07-28
		8	Metal Ions	Disposable hemoperfutor YY/T0464-2019 5.6.2		2026-07-28
		9	PH	Disposable hemoperfutor YY/T0464-2019 5.6.3		2026-07-28
		10	Residue on Evaporation	Disposable hemoperfutor YY/T0464-2019 5.6.4		2026-07-28
		11	Ultraviolet Absorbance	Disposable hemoperfutor YY/T0464-2019 5.6.5		2026-07-28
		12	Biological evaluation	Disposable hemoperfutor YY/T 0464-2019 5.7		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Sterility	Disposable hemoperfutor YY/T 0464-2019 5.8		2026-07-28
		14	Pyrogen	Disposable hemoperfutor YY/T 0464-2019 5.9		2026-07-28
		15	Bacterial endotoxins	Disposable hemoperfutor YY/T 0464-2019 5.10		2026-07-28
		16	sealing performance	Disposable hemoperfutor YY/T 0464-2019 5.11		2026-07-28
		17	Adsorption performance	Disposable hemoperfutor YY/T 0464-2019 5.12		2026-07-28
		18	temperature resistance	Disposable hemoperfutor YY/T 0464-2019 5.13		2026-07-28
		19	period of validity	Disposable hemoperfutor YY/T 0464-2019 5.14		2026-07-28
103	Disposable membrane plasmaseparator and plasma component separator	1	All items	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019		2026-07-28
		2	appearance	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.1		2026-07-28
		3	Effective membrane area of plasma separator and plasma component separator	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.2		2026-07-28
		4	Plasma separator blood chamber capacity and plasma component separator plasma chamber capacity	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.3		2026-07-28
		5	Basic dimensions of plasma separators	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			and plasma component separators			
		6	particle shedding	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.5		2026-07-28
		7	Reducing Substances	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.1		2026-07-28
		8	Metal Ions	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.2		2026-07-28
		9	Acid-Base Titration	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.3		2026-07-28
		10	Residue on Evaporation	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.4		2026-07-28
		11	Ultraviolet Absorbance	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.5		2026-07-28
		12	Ethylene Oxide Residue	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.6.6		2026-07-28
		13	Biological evaluation	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.7		2026-07-28
		14	Sterility	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.8		2026-07-28
		15	Pyrogen	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.9		2026-07-28
		16	Bacterial endotoxins	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.10		2026-07-28
		17	Separation of hemoglobin content in plasma by plasma separator	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.11		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	sealing performance	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.12		2026-07-28
		19	Plasma filtration rate	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.13.1		2026-07-28
		20	protein screening coefficient	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.13.2		2026-07-28
		21	Plasma component separator plasma component filtration rate	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.13.3		2026-07-28
		22	Screening coefficient of plasma component separator protein	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.13.4		2026-07-28
		23	temperature resistance	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.14		2026-07-28
		24	period of validity	Disposable membrane plasmaseparator and plasma component separator YY 0465-2019 5.15		2026-07-28
104	A.V.fistula needle sets for single use	1	All items	A.V.fistula needle sets for single use YY/T 0328-2015		2026-07-28
		2	particle contamination	A.V.fistula needle sets for single use YY/T 0328-2015 5.1		2026-07-28
		3	Sealing performance	A.V.fistula needle sets for single use YY/T 0328-2015 5.2		2026-07-28
		4	connection strength	A.V.fistula needle sets for single use YY/T 0328-2015 5.3		2026-07-28
		5	flow	A.V.fistula needle sets for single use YY/T 0328-2015 5.4		2026-07-28
		6	hose	A.V.fistula needle sets for single use YY/T 0328-2015 5.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	puncture needle	A.V.fistula needle sets for single use YY/T 0328-2015 5.6		2026-07-28
		8	Stop clamp	A.V.fistula needle sets for single use YY/T 0328-2015 5.7		2026-07-28
		9	Inner cone joint	A.V.fistula needle sets for single use YY/T 0328-2015 5.8		2026-07-28
		10	protective sheath	A.V.fistula needle sets for single use YY/T 0328-2015 5.9		2026-07-28
		11	Anti needle puncture protection device	A.V.fistula needle sets for single use YY/T 0328-2015 5.10		2026-07-28
		12	Reducing Substances	A.V.fistula needle sets for single use YY/T 0328-2015 6.2		2026-07-28
		13	Metal Ions	A.V.fistula needle sets for single use YY/T 0328-2015 6.3		2026-07-28
		14	Acid-Base Titration	A.V.fistula needle sets for single use YY/T 0328-2015 6.4		2026-07-28
		15	Residue on Evaporation	A.V.fistula needle sets for single use YY/T 0328-2015 6.5		2026-07-28
		16	Ultraviolet Absorbance	A.V.fistula needle sets for single use YY/T 0328-2015 6.6		2026-07-28
		17	Ethylene Oxide Residue	A.V.fistula needle sets for single use YY/T 0328-2015 6.7		2026-07-28
		18	Biological evaluation	A.V.fistula needle sets for single use YY/T 0328-2015 7.1		2026-07-28
		19	Sterility	A.V.fistula needle sets for single use YY/T 0328-2015 7.2		2026-07-28
		20	Bacterial endotoxins	A.V.fistula needle sets for single use YY/T 0328-2015 7.3		2026-07-28
105	Cardiopulmonary bypass	1	All items	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	systems—Blood-gas exchangers(oxygenators)	2	Sterility and Pyrogen	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.1.1		2026-07-28
		3	Biological evaluation	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.1.2		2026-07-28
		4	Tightness of blood channels	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.2.1		2026-07-28
		5	Tightness of liquid channels in heat exchangers	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.2.2		2026-07-28
		6	Blood volume	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.2.3		2026-07-28
		7	joint	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.2.4		2026-07-28
		8	Performance characteristics	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.3		2026-07-28
		9	Reducing Substances	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.1		2026-07-28
		10	Metal Ions	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.2		2026-07-28
		11	Acid-Base Titration	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.3		2026-07-28
		12	Residue on Evaporation	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.4		2026-07-28
		13	Ultraviolet Absorbance	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.5		2026-07-28
		14	Color	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.6		2026-07-28
		15	Ethylene Oxide Residue	Cardiopulmonary bypass systems—Blood-gas exchangers(oxygenators) YY 0604-2016 5.4.7		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
106	Cardiopulmonary bypass systems -Water heating/cooling system	1	Partial items	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017	Except for safety requirements and environmental testing	2026-07-28
		2	Appearance and structure	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.2		2026-07-28
		3	Connection firmness	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.3		2026-07-28
		4	capacity	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.4		2026-07-28
		5	flow	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.5		2026-07-28
		6	temperature control	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.6		2026-07-28
		7	temperature display	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.7		2026-07-28
		8	Over temperature prompt	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.8		2026-07-28
		9	Prompt for water rise/fall rate	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.9		2026-07-28
		10	noise	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.10		2026-07-28
		11	Prompt sound	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.11		2026-07-28
		12	leakage	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.12		2026-07-28
		13	line pressure	Cardiopulmonary bypass systems -Water heating/cooling system GB 12263-2017 4.13		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
107	Haemodialysers,haemodiafilters,haemofilters	1	All items	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016		2026-07-28
		2	Biological evaluation	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.1		2026-07-28
		3	Sterility	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.2		2026-07-28
		4	Pyrogen	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.3		2026-07-28
		5	Mechanical properties	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.4		2026-07-28
		6	Usage performance	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.5		2026-07-28
		7	Reducing Substances	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.1		2026-07-28
		8	Metal Ions	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.2		2026-07-28
		9	PH	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.3		2026-07-28
		10	Residue on Evaporation	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Ultraviolet Absorbance	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.5		2026-07-28
		12	Ethylene Oxide Residue	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.6		2026-07-28
108	Extracorporeal blood circuit for blood purification devices	1	All items	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016		2026-07-28
		2	Biological evaluation	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.1		2026-07-28
		3	Sterility	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.2		2026-07-28
		4	Pyrogen	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.3		2026-07-28
		5	Mechanical properties	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.4		2026-07-28
		6	Blood path compliance	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.5		2026-07-28
		7	particle contamination	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.6		2026-07-28
		8	Reducing Substances	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.1		2026-07-28
		9	Heavy Metals	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.2		2026-07-28
		10	Acid-Base Titration	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.3		2026-07-28
		11	Residue on Evaporation	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.4		2026-07-28
		12	Ultraviolet Absorbance	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Color	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.6		2026-07-28
		14	Ethylene Oxide Residue	Hemodialysis and related therapies—Extracorporeal blood circuit for blood purification devices YY 0267-2016 4.7.7		2026-07-28
109	haemoconcentrators	1	All items	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016		2026-07-28
		2	Biological evaluation	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.1		2026-07-28
		3	Sterility	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.2		2026-07-28
		4	Pyrogen	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.3		2026-07-28
		5	Mechanical properties	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.4		2026-07-28
		6	Usage performance	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.5		2026-07-28
		7	Reducing Substances	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.1		2026-07-28
		8	Metal Ions	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.2		2026-07-28
		9	PH	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and		2026-07-28

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SCHEDULE OF ACCREDITATION(ATTACHMENT TO CERTIFICATE)

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				haemoconcentrators YY 0053-2016 3.6.3		
		10	Residue on Evaporation	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.4		2026-07-28
		11	Ultraviolet Absorbance	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.5		2026-07-28
		12	Ethylene Oxide Residue	Hemodialysis and relevant therapies—Haemodialysers,haemodiafilters,haemofilters and haemoconcentrators YY 0053-2016 3.6.6		2026-07-28
110	Water for haemodialysis and related therapies	1	All items	Water for haemodialysis and related therapies YY 0572-2015		2026-07-28
		2	Microbial requirements	Water for haemodialysis and related therapies YY 0572-2015 4.1		2026-07-28
		3	Chemical Contaminants	Waters for haemodialysis and related therapies YY 0572-2015 4.2		2026-07-28
111	Concentrates for haemodialysis and related therapies	1	All items	Concentrates for haemodialysis and related therapies YY 0598-2015	Only used when cited or requested by a customer	2026-07-28
		2	character	Concentrates for haemodialysis and related therapies YY 0598-2015 5.1		2026-07-28
		3	Solute Concentration	Concentrates for haemodialysis and related therapies YY 0598-2015 5.2		2026-07-28
		4	Microbial limit	Concentrates for haemodialysis and related therapies YY 0598-2015 5.3		2026-07-28
		5	Bacterial endotoxins	Concentrates for haemodialysis and related therapies YY 0598-2015 5.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	content	Concentrates for haemodialysis and related therapies YY 0598-2015 5.5		2026-07-28
		7	particle contamination	Concentrates for haemodialysis and related therapies YY 0598-2015 5.6		2026-07-28
112	Surgical instruments-Non-cutting,articulated instruments	1	All items	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022		2026-07-28
		2	Heat treatment and hardness of components	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.1		2026-07-28
		3	corrosion resistance	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.2		2026-07-28
		4	manufacturing process	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.3		2026-07-28
		5	Surface Condition	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.4		2026-07-28
		6	elasticity	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.5		2026-07-28
		7	Clamping function	Surgical instruments-Non-cutting,articulated instruments-General requirements and test methods GB/T 2766-2022 5.6		2026-07-28
113	Surgical instruments-Non-cutting, articulated instruments-General specifications	1	All items	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008	Only used when cited or requested by a customer	2026-07-28
		2	hardness	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.1	Only used when cited or requested by a	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					customer	
		3	Manufacturing process and performance	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.2	Only used when cited or requested by a customer	2026-07-28
		4	appearance	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.3.1	Only used when cited or requested by a customer	2026-07-28
		5	Surface roughness	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.3.2	Only used when cited or requested by a customer	2026-07-28
		6	Corrosion Resistance	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.3.3	Only used when cited or requested by a customer	2026-07-28
		7	elasticity	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.4	Only used when cited or requested by a	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					customer	
		8	Clamping function	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.5	Only used when cited or requested by a customer	2026-07-28
		9	strength	Surgical instruments-Non-cutting, articulated instruments-General specifications YY/T 0687-2008 4.6	Only used when cited or requested by a customer	2026-07-28
114	Scalpel blade	1	All items	Scalpel blade YY 0174-2019		2026-07-28
		2	size	Scalpel blade YY 0174-2019 4.1		2026-07-28
		3	appearance	Scalpel blade YY 0174-2019 4.2		2026-07-28
		4	Blade sharpness	Scalpel blade YY 0174-2019 4.3		2026-07-28
		5	hardness	Scalpel blade YY 0174-2019 4.4		2026-07-28
		6	elasticity	Scalpel blade YY 0174-2019 4.5		2026-07-28
		7	Rust prevention performance	Scalpel blade YY 0174-2019 4.6		2026-07-28
		8	Sterility	Scalpel blade YY 0174-2019 4.7		2026-07-28
		9	Ethylene Oxide	Scalpel blade YY 0174-2019 4.8		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Residue			
115	Surgical scissors-General specifications	1	All items	Surgical scissors-General specifications YY/T 0176-2006		2026-07-28
		2	screw	Surgical scissors-General specifications YY/T 0176-2006 4.1		2026-07-28
		3	cutting edge	Surgical scissors-General specifications YY/T 0176-2006 4.2		2026-07-28
		4	Blade contact point	Surgical scissors-General specifications YY/T 0176-2006 4.3		2026-07-28
		5	Shear performance test	Surgical scissors-General specifications YY/T 0176-2006 4.4		2026-07-28
		6	hardness test	Surgical scissors-General specifications YY/T 0176-2006 4.5		2026-07-28
		7	Surface roughness test	Surgical scissors-General specifications YY/T 0176-2006 4.6		2026-07-28
		8	Corrosion resistance test	Surgical scissors-General specifications YY/T 0176-2006 4.7		2026-07-28
		9	appearance	Surgical scissors-General specifications YY/T 0176-2006 4.8		2026-07-28
116	General specification for medical forceps	1	All items	General specification for medical forceps YY/T 0295.1-2005		2026-07-28
		2	size test	General specification for medical forceps YY/T 0295.1-2005 4.1		2026-07-28
		3	hardness test	General specification for medical forceps YY/T 0295.1-2005 4.2		2026-07-28
		4	appearance test	General specification for medical forceps YY/T 0295.1-2005 4.3		2026-07-28
		5	Elasticity test	General specification for medical forceps YY/T 0295.1-2005 4.4		2026-07-28
		6	Connection firmness test	General specification for medical forceps YY/T 0295.1-2005 4.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Labial head teeth	General specification for medical forceps YY/T 0295.1-2005 4.6		2026-07-28
		8	Head contact	General specification for medical forceps YY/T 0295.1-2005 4.7		2026-07-28
		9	Guide pin, positioning pin	General specification for medical forceps YY/T 0295.1-2005 4.8		2026-07-28
		10	Handle pattern	General specification for medical forceps YY/T 0295.1-2005 4.9		2026-07-28
		11	Corrosion resistance test	General specification for medical forceps YY/T 0295.1-2005 4.10		2026-07-28
		12	Surface roughness test	General specification for medical forceps YY/T 0295.1-2005 4.11		2026-07-28
117	Hose biopsy sampling forceps used with endoscope--General specifications	1	All items	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006		2026-07-28
		2	usage performance	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.1		2026-07-28
		3	hardness	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.2		2026-07-28
		4	surface roughness	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.3		2026-07-28
		5	appearance	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.4		2026-07-28
		6	size	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.5		2026-07-28
		7	Corrosion resistance	Hose biopsy sampling forceps used with endoscope--General specifications YY/T 1076-2004,XG1-2006 4.6		2026-07-28
118	Disposable ECG electrodes	1	Partial items	Disposable ECG electrodes YY/T 0196-2005 4.3.1	Only biological reactions	2026-07-28
119	Medical ultrasonic	1	Partial items	Medical ultrasonic couplants YY/T 0299-2022	Except for ound	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	couplants				velocity, acoustic characteristic impedance, and acoustic attenuation parameters	
		2	Sterility	Medical ultrasonic couplants YY/T 0299-2022 5.1.1		2026-07-28
		3	Microbial limit	Medical ultrasonic couplants YY/T 0299-2022 5.1.2		2026-07-28
		4	Biological evaluation	Medical ultrasonic couplants YY/T 0299-2022 5.2		2026-07-28
		5	viscosity	Medical ultrasonic couplants YY/T 0299-2022 5.3		2026-07-28
		6	pH	Medical ultrasonic couplants YY/T 0299-2022 5.3		2026-07-28
		7	appearance	Medical ultrasonic couplants YY/T 0299-2022 5.4		2026-07-28
120	Hot compress sticker (bag）	1	All items	Hot compress sticker (bag） YY 0060-2018		2026-07-28
		2	size	Hot compress sticker (bag） YY 0060-2018 5.1		2026-07-28
		3	appearance	Hot compress sticker (bag） YY 0060-2018 5.2		2026-07-28
		4	Sealing of outer packaging	Hot compress sticker (bag） YY 0060-2018 5.3		2026-07-28
		5	Inner bag anti drop	Hot compress sticker (bag） YY 0060-2018 5.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	Tensile strength of packaging bags	Hot compress sticker (bag） YY 0060-2018 5.5		2026-07-28
		7	Moisture permeability of the outer bag	Hot compress sticker (bag） YY 0060-2018 5.6.1		2026-07-28
		8	Oxygen permeability of the outer bag	Hot compress sticker (bag） YY 0060-2018 5.6.2		2026-07-28
		9	Adhesive performance	Hot compress sticker (bag） YY 0060-2018 5.7		2026-07-28
		10	Temperature	Hot compress sticker (bag） YY 0060-2018 5.8		2026-07-28
		11	Biological evaluation	Hot compress sticker (bag） YY 0060-2018 5.9		2026-07-28
121	hazardous substances in electronic information products	1	All items	Testing methods for hazardous substances in electronic information products SJ/T 11365-2006		2026-07-28
		2	Toxic and Hazardous Substances	Testing methods for hazardous substances in electronic information products SJ/T 11365-2006 5		2026-07-28
		3	Polybrominated Biphenyls and Polybrominated Diphenyl Ethers	Testing methods for hazardous substances in electronic information products SJ/T 11365-2006 6		2026-07-28
		4	Lead, cadmium, and mercury	Testing methods for hazardous substances in electronic information products SJ/T 11365-2006 7		2026-07-28
		5	Hexavalent Chromium	Testing methods for hazardous substances in electronic information products SJ/T 11365-2006 8		2026-07-28
122	Ophthalmic optics-Intraocular	1	All items	Ophthalmic optics-Intraocular lenses-Part 1：Terminology YY/T0290.1-2021		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	lenses	2	Partial items	Ophthalmic optics-Intraocular lenses-Part2：Optical properties and test methods YY 0290.2-2021	Except for MTF using model	2026-07-28
		3	Optical power	Ophthalmic optics-Intraocular lenses-Part2：Optical properties and test methods YY 0290.2-2021 4.2		2026-07-28
		4	Image quality	Ophthalmic optics-Intraocular lenses-Part2：Optical properties and test methods YY 0290.2-2021 4.3		2026-07-28
		5	Spectral transmittance	Ophthalmic optics-Intraocular lenses-Part2：Optical properties and test methods YY 0290.2-2021 4.4		2026-07-28
		6	Partial items	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018	Except for Gap analysis	2026-07-28
		7	Dimensions and tolerances	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 4.2		2026-07-28
		8	Compressive force	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 4.4		2026-07-28
		9	Axial displacement under compressive force	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 4.5		2026-07-28
		10	Optical eccentricity	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 4.6		2026-07-28
		11	Optical inclination angle	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 4.7		2026-07-28
		12	contact angle	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 4.8		2026-07-28
		13	Compression force attenuation	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 4.9		2026-07-28
		14	Dynamic fatigue durability	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 4.10		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Surgical procedures	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 4.11		2026-07-28
		16	Surface and material uniformity	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 4.12		2026-07-28
		17	Performance recovery of simulated surgical procedures	Ophthalmic optics-Intraocular lenses-Part3：Mechanical properties and test methods YY 0290.3-2018 5		2026-07-28
		18	All items	Ophthalmic optics-Intraocular lenses-Part 4：Labeling and information YY/T 0290.4-2022		2026-07-28
		19	All items	Ophthalmic optics-Intraocular lenses-Part 6：Shelf-life and transport stability YY/T0290.6-2021		2026-07-28
		20	All items	Ophthalmic optics-Intraocular lenses-Part 8：Fundamental requirement YY0290.8-2022		2026-07-28
		21	Optical and mechanical properties	Ophthalmic optics-Intraocular lenses-Part 8：Fundamental requirement YY0290.8-2022 5		2026-07-28
		22	Biocompatibility	Ophthalmic optics-Intraocular lenses-Part 8：Fundamental requirement YY0290.8-2022 6		2026-07-28
		23	Sterilization	Ophthalmic optics-Intraocular lenses-Part 8：Fundamental requirement YY0290.8-2022 9		2026-07-28
		24	All items	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010	Only used when cited or requested by a customer	2026-07-28
		25	general requirements	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY0290.9-2010 4.1	Only used when cited	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					or requested by a customer	
		26	Dimensions and tolerances	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 4.2	Only used when cited or requested by a customer	2026-07-28
		27	general requirements	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 5.1	Only used when cited or requested by a customer	2026-07-28
		28	Optical power	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 5.2	Only used when cited or requested by a customer	2026-07-28
		29	Image quality	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 5.3	Only used when cited or requested by a customer	2026-07-28
		30	Optical Design	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 5.4.1	Only used when cited	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					or requested by a customer	
		31	Spectral transmission characteristics	Ophthalmic implants-Intraocular lenses-Part 9: Multifocal intraocular lenses YY 0290.9-2010 5.4.2		2026-07-28
123	Ophthalmic optics-Contact lenses Rigid contact lenses specification	1	Partial items	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012	Except for rabbit eye compatibility experiment	2026-07-28
		2	Rear vertex power, column mirror power, and column mirror axis position	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.2.2		2026-07-28
		3	Prismatic degree	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.2.3		2026-07-28
		4	Maximum deviation of optical center	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.2.4		2026-07-28
		5	Transmittance performance	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.2.5		2026-07-28
		6	Geometric dimension requirements	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.3		2026-07-28
		7	refractivity	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.2.1		2026-07-28
		8	oxygen permeability	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.2.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	hardness	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.2.3		2026-07-28
		10	contact angle	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.2.4		2026-07-28
		11	Mechanical	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.2.5		2026-07-28
		12	Extraction Experiment	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.3.1		2026-07-28
		13	Ingestion and release of preservatives	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.3.2		2026-07-28
		14	Fading Test	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.4.3.3		2026-07-28
		15	Biocompatibility evaluation	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.5		2026-07-28
		16	Acute systemic toxicity	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.5.2		2026-07-28
		17	Eye irritation test	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.5.3		2026-07-28
		18	Cytotoxicity	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.5.4		2026-07-28
		19	Sensitization	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.5.5		2026-07-28
		20	Microbial limit	Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.6		2026-07-28
		21		Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.7		2026-07-28
		22		Ophthalmic optics-Contact lenses-Part 2:Rigid contact lenses specification GB 11417.2-2012 4.8		2026-07-28

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		№	Item/ Parameter			
124	Ophthalmic optics — Contact lenses Soft contact lenses	1	Partial items	Ophthalmic optics-Contact lenses-Part 3:Soft contact lenses GB 11417.3-2012	Except for rabbit eye compatibility experiment	2026-07-28
		2	Rear vertex power, column mirror power, and column mirror axis position	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.2.2		2026-07-28
		3	Prismatic degree	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.2.3		2026-07-28
		4	Transmittance performance	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.2.4		2026-07-28
		5	Geometric dimension requirements	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.3		2026-07-28
		6	Geometric dimension requirements	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.2.1		2026-07-28
		7	water content	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.2.2		2026-07-28
		8	Oxygen permeability	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.2.3		2026-07-28
		9	fading test	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.2.4		2026-07-28
		10	extraction test	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.3.1		2026-07-28
		11	Ingestion and release of preservatives	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.4.3.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Acute systemic toxicity	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.5.2		2026-07-28
		13	Acute eye irritation test	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.5.3		2026-07-28
		14	Cytotoxicity	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.5.4		2026-07-28
		15	Sensitization	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.5.5		2026-07-28
		16	Microbial requirements	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.6		2026-07-28
		17	stability	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.7		2026-07-28
		18	Internal quality and surface defects	Ophthalmic optics-Contact lenses-Part3:Soft contact lenses GB 11417.3-2012 4.8		2026-07-28
125	Medical sodium hyaluronate gel	1	All items	Medical sodium hyaluronate gel YY/T 0308-2015		2026-07-28
		2	appearance	Medical sodium hyaluronate gel YY/T 0308-2015 5.1		2026-07-28
		3	Effective usage	Medical sodium hyaluronate gel YY/T 0308-2015 5.2		2026-07-28
		4	Identification	Medical sodium hyaluronate gel YY/T0308-2015 5.3		2026-07-28
		5	Content	Medical sodium hyaluronate gel YY/T0308-2015 5.4		2026-07-28
		6	transmittance	Medical sodium hyaluronate gel YY/T0308-2015 5.5		2026-07-28
		7	pH	Medical sodium hyaluronate gel YY/T0308-2015 5.6		2026-07-28
		8	Osmotic Pressure	Medical sodium hyaluronate gel YY/T0308-2015 5.7		2026-07-28

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		№	Item/ Parameter			
		9	Shear viscosity	NIedical sodium hyaluronate gel YY/T 0308-2015 5.8		2026-07-28
		10	elasticity	NIedical sodium hyaluronate gel YY/T 0308-2015 5.9		2026-07-28
		11	Inherent Viscosity	Medical sodium hyaluronate gel YY/T0308-2015 5.10.1		2026-07-28
		12	Average molecular weight and molecular weight distribution coefficient	NIedical sodium hyaluronate gel YY/T 0308-2015 5.10.2		2026-07-28
		13	Protein Content	Medical sodium hyaluronate gel YY/T0308-2015 5.11		2026-07-28
		14	Ultraviolet Absorbance	Medical sodium hyaluronate gel YY/T0308-2015 5.12		2026-07-28
		15	Refractive index	Medical sodium hyaluronate gel YY/T0308-2015 5.13		2026-07-28
		16	Heavy Metal Content	Medical sodium hyaluronate gel YY/T0308-2015 5.14		2026-07-28
		17	Ethanol Residue	Medical sodium hyaluronate gel YY/T0308-2015 5.15		2026-07-28
		18	Sterility	Medical sodium hyaluronate gel YY/T 0308-2015 5.16		2026-07-28
		19	Bacterial endotoxins	Medical sodium hyaluronate gel YY/T 0308-2015 5.17		2026-07-28
		20	Hemolysis test	Medical sodium hyaluronate gel YY/T 0308-2015 5.18		2026-07-28
		21	Biological evaluation	Medical sodium hyaluronate gel YY/T 0308-2015 5.19		2026-07-28
126	General specification	1	Partial items	General specification for mediacl oxygen generator with molecular sieve YY/T 0298-1998	Except for air	2026-07-28

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		№	Item/ Parameter			
	for mediacl oxygen generator with molecular sieve				tightness, noise, moisture content, oxygen output, environmental testing, indicator lights；Use only when quoted or requested by the customer	
		2	appearance	General specification for mediacl oxygen generator with molecular sieve YY/T 0298-1998 5.1		2026-07-28
		3	Oxygen Concentration	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.1		2026-07-28
		4	Carbon Dioxide Content	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.3		2026-07-28
		5	Carbon Monoxide Content	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.4		2026-07-28
		6	Gaseous Acid and Alkali Content	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.5		2026-07-28
		7	Ozone and Other Gaseous Oxidants Content	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.6		2026-07-28
		8	smell	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.7		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	Solid particle size	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.8		2026-07-28
		10	Solid Matter Content	General specification for medical oxygen generator with molecular sieve YY/T0298-1998 5.2.9		2026-07-28
127	Capsular tension ring	1	All items	Ophthalmic optical-Capsular tension ring YY 0762-2017		2026-07-28
		2	Functional elasticity	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.1.1		2026-07-28
		3	Deformation and stress	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.1.2		2026-07-28
		4	Uniformity	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.1.3		2026-07-28
		5	Dynamic fatigue durability	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.1.4		2026-07-28
		6	size	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.2		2026-07-28
		7	surface quality	Ophthalmic optical-Capsular tension ring YY 0762-2017 4.3		2026-07-28
		8	Extraction	Ophthalmic optical-Capsular tension ring YY0762-2017 4.4		2026-07-28
		9	Cytotoxicity	Ophthalmic optical-Capsular tension ring YY 0762-20171 4.5.2		2026-07-28
		10	Eye irritation test	Ophthalmic optical-Capsular tension ring YY 0762-20171 4.5.3		2026-07-28
		11	Sensitization	Ophthalmic optical-Capsular tension ring YY 0762-20171 4.5.4		2026-07-28
		12	local effects of eye after Implantation	Ophthalmic optical-Capsular tension ring YY 0762-20171 4.5.5		2026-07-28
		13	Sterility	Ophthalmic optical-Capsular tension ring YY 0762-20171 4.6		2026-07-28
		14	Ethylene Oxide Residue	Ophthalmic optical-Capsular tension ring YY0762-2017 4.7		2026-07-28

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		№	Item/ Parameter			
128	Endovascular prostheses	1	Partial items	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014	Use only when quoted or requested by the customer.Except for visibility and MRI compatibility	2026-07-28
		2	Bond strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.2	Use only when quoted or requested by the customer	2026-07-28
		3	Component compatibility	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.3	Use only when quoted or requested by the customer	2026-07-28
		4	Size	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.4	Use only when quoted or requested by the customer	2026-07-28
		5	Bending/Discounting	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.5	Use only when	2026-07-28

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		№	Item/ Parameter			
					quoted or requested by the customer	
		6	Profile	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.6	Use only when quoted or requested by the customer	2026-07-28
		7	Pushability	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.7	Use only when quoted or requested by the customer	2026-07-28
		8	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.9	Use only when quoted or requested by the customer	2026-07-28
		9	Torsion	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.10	Use only when quoted or requested by the customer	2026-07-28
		10	Torsional bonding strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.11	Use only when	2026-07-28

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		№	Item/ Parameter			
					quoted or requested by the customer	
		11	traceability	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.1.12	Use only when quoted or requested by the customer	2026-07-28
		12	Bond strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.2	Use only when quoted or requested by the customer	2026-07-28
		13	Balloon inflation time	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.3	Use only when quoted or requested by the customer	2026-07-28
		14	Balloon decompression time	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.4	Use only when quoted or requested by the customer	2026-07-28
		15	Mean Burst Pressure of Balloon	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.5	Use only when	2026-07-28

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		№	Item/ Parameter			
					quoted or requested by the customer	
		16	Rated burst pressure of balloon	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.6	Use only when quoted or requested by the customer	2026-07-28
		17	Balloon rated fatigue	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.7	Use only when quoted or requested by the customer	2026-07-28
		18	Component size compatibility	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.8	Use only when quoted or requested by the customer	2026-07-28
		19	Dimensional verification	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.9	Use only when quoted or requested by the customer	2026-07-28
		20	release force	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.10	Use only when	2026-07-28

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		№	Item/ Parameter			
					quoted or requested by the customer	
		21	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.12	Use only when quoted or requested by the customer	2026-07-28
		22	Torsional bonding strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.13	Use only when quoted or requested by the customer	2026-07-28
		23	Tensile strength of pipes	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.2.14	Use only when quoted or requested by the customer	2026-07-28
		24	Bond strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.2	Use only when quoted or requested by the customer	2026-07-28
		25	Component size compatibility	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.3	Use only when	2026-07-28

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		№	Item/ Parameter			
					quoted or requested by the customer	
		26	Dimensional verification	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.4	Use only when quoted or requested by the customer	2026-07-28
		27	Bending/Discounting	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.5	Use only when quoted or requested by the customer	2026-07-28
		28	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.7	Use only when quoted or requested by the customer	2026-07-28
		29	Torsional bonding strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.8	Use only when quoted or requested by the customer	2026-07-28
		30	Tensile strength of pipes	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.3.9	Use only when	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					quoted or requested by the customer	
		31	Biological evaluation	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.4	Use only when quoted or requested by the customer	2026-07-28
		32	hemostatic	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.2.5	Use only when quoted or requested by the customer	2026-07-28
		33	The relationship between implant length and diameter	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.1.2	Use only when quoted or requested by the customer	2026-07-28
		34	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.1.4	Use only when quoted or requested by the customer	2026-07-28
		35	Wall adhesion	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.2	Use only when	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					quoted or requested by the customer	
		36	Anti extrusion performance	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.3	Use only when quoted or requested by the customer	2026-07-28
		37	Local compression	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.4	Use only when quoted or requested by the customer	2026-07-28
		38	Anti displacement performance	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.5	Use only when quoted or requested by the customer	2026-07-28
		39	Radial support force	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.6	Use only when quoted or requested by the customer	2026-07-28
		40	Retract	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.7	Use only when	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					quoted or requested by the customer	
		41	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.2.8	Use only when quoted or requested by the customer	2026-07-28
		42	Rupture/circumferential strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.2	Use only when quoted or requested by the customer	2026-07-28
		43	corrosion	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.3	Use only when quoted or requested by the customer	2026-07-28
		44	Processing fit strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.4	Use only when quoted or requested by the customer	2026-07-28
		45	durability	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.5	Use only when	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					quoted or requested by the customer	
		46	Axial tensile strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.6	Use only when quoted or requested by the customer	2026-07-28
		47	Strength after repeated puncture	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.7	Use only when quoted or requested by the customer	2026-07-28
		48	bonding strength	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.3.8	Use only when quoted or requested by the customer	2026-07-28
		49	Pores, water permeability, and water osmotic pressure	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.4.2	Use only when quoted or requested by the customer	2026-07-28
		50	Overall water permeability/leakag	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.4.3	Use only when	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			e rate		quoted or requested by the customer	
		51	Dimensional verification	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.5.2	Use only when quoted or requested by the customer	2026-07-28
		52	Bending/Discounting	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.5.3	Use only when quoted or requested by the customer	2026-07-28
		53	Anti displacement performance	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.5.4	Use only when quoted or requested by the customer	2026-07-28
		54	Tensile testing of module components	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.5.5	Use only when quoted or requested by the customer	2026-07-28
		55	The relationship between implant	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.6.2	Use only when	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			length and diameter in size selection		quoted or requested by the customer	
		56	Size	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.6.3	Use only when quoted or requested by the customer	2026-07-28
		57	Retract	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.6.4	Use only when quoted or requested by the customer	2026-07-28
		58	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.6.5	Use only when quoted or requested by the customer	2026-07-28
		59	Implant diameter and balloon filling pressure	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.6.6	Use only when quoted or requested by the customer	2026-07-28
		60	Radial support force	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.2	Use only when	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					quoted or requested by the customer	
		61	Anti extrusion performance	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.3	Use only when quoted or requested by the customer	2026-07-28
		62	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.4	Use only when quoted or requested by the customer	2026-07-28
		63	Blank surface area of bracket	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.5	Use only when quoted or requested by the customer	2026-07-28
		64	Local compression	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.6	Use only when quoted or requested by the customer	2026-07-28
		65	Bending/Discounting	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 7.3.7.7	Use only when	2026-07-28

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		№	Item/ Parameter			
					quoted or requested by the customer	
129	Vena cava filters	1	All items	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016	Except for MRI and visibility	2026-07-28
		2	Size	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 4.2		2026-07-28
		3	Catheter rupture	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.2		2026-07-28
		4	Dimensional verification and component dimensional compatibility	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.3		2026-07-28
		5	Pressurized injection	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.4		2026-07-28
		6	simulated use	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.5		2026-07-28
		7	tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.6		2026-07-28
		8	Torsional bonding performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.1.7		2026-07-28
		9	Dimensional verification and component dimensional compatibility	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.2.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	release force	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.2.3		2026-07-28
		11	simulated use	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.2.4		2026-07-28
		12	tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.2.5		2026-07-28
		13	Torsional bonding strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.2.6		2026-07-28
		14	corrosion	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.3		2026-07-28
		15	durability	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.4		2026-07-28
		16	Filter size verification	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.5		2026-07-28
		17	Filter tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.6		2026-07-28
		18	Anti displacement performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.7		2026-07-28
		19	Radial support force	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.9		2026-07-28
		20	Visual inspection	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.3.10		2026-07-28
		21	Filter tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.4.2		2026-07-28
		22	Recycling/conversion force	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.4.3		2026-07-28
		23	matching performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.4.4.2		2026-07-28
		24	Recycling performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.4.4.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		25	Conversion performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.4.4.4		2026-07-28
		26	Catheter rupture	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.5.2		2026-07-28
		27	Dimensional verification and component dimensional compatibility	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.5.3		2026-07-28
		28	Pressurized injection	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.5.4		2026-07-28
		29	simulated use	Cardiovascular implant-Endovascular devices-Part 1:Endovascular prostheses YY/T 0663.1-2014 8.5.5.5		2026-07-28
		30	tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.5.6		2026-07-28
		31	Torsional bonding performance	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.5.7		2026-07-28
		32	Dimensional verification and component dimensional compatibility	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.6.2		2026-07-28
		33	Recycling/conversion force	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.6.3		2026-07-28
		34	simulated use	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.6.4		2026-07-28
		35	Torsional bonding strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.6.5		2026-07-28
		36	tensile strength	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.6.6		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		37	biocompatibility	Cardiovascular implants-Endovascular devices- Part 3: Vena cava filters YY/T 0663.3-2016 8.5.7.2		2026-07-28
130	Cardiovascular implants-Cardiac occluder	1	Partial items	Cardiovascular implants-Cardiac occluder YY/T 1553-2017	Except for MRI and visibility	2026-07-28
		2	Size	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 4.2		2026-07-28
		3	appearance	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.2		2026-07-28
		4	particle contamination	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.3		2026-07-28
		5	size	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.4		2026-07-28
		6	corrosion	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.5		2026-07-28
		7	Tensile strength of cardiac occluder	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.6		2026-07-28
		8	stability	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.7		2026-07-28
		9	Pore or flow resistance	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.8		2026-07-28
		10	durability	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.11		2026-07-28
		11	Chemical Properties	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.2.12		2026-07-28
		12	appearance	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.2		2026-07-28
		13	size	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.3		2026-07-28
		14	tensile strength	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Torsional bonding strength	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.5		2026-07-28
		16	Bending/Discounting	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.6		2026-07-28
		17	hemostatic	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.7		2026-07-28
		18	Corrosion Resistance	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.8		2026-07-28
		19	Chemical Properties	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.3.10		2026-07-28
		20	bonding strength	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.4.2		2026-07-28
		21	Bending	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.4.3		2026-07-28
		22	simulated use	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 8.4.4		2026-07-28
		23	Sterility	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 11.1		2026-07-28
		24	Microbial limit	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 11.2		2026-07-28
		25	Residual Sterilants	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 11.3		2026-07-28
		26	bacterial endotoxin/pyrogen	Cardiovascular implants-Cardiac occluder YY/T 1553-2017 11.4		2026-07-28
131	Cross-linked sodium hyaluronate gel for plastic surgery	1	All items	Cross-linked sodium hyaluronate gel for plastic surgery YY/T 0962-2021		2026-07-28
		2	appearance	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.1		2026-07-28
		3	Effective usage	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Particle size distribution	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.3		2026-07-28
		5	Pushing force	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.4		2026-07-28
		6	Infrared identification	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.5		2026-07-28
		7	Swelling	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.6		2026-07-28
		8	osmotic pressure	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.7		2026-07-28
		9	pH value	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.8		2026-07-28
		10	Sodium hyaluronate content	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.9		2026-07-28
		11	protein	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.10		2026-07-28
		12	Total heavy metals	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.11		2026-07-28
		13	Residual amount of crosslinking agent	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.12		2026-07-28
		14	Free Sodium hyaluronate content	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.13		2026-07-28
		15	other additives	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.14		2026-07-28
		16	Sterility	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.15		2026-07-28
		17	bacterial endotoxin	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.16		2026-07-28
		18	Hemolytic Streptolysin	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.17		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		19	biological evaluation	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.18		2026-07-28
		20	biodegradability	Cross-linked sodium hyaluronate gel for plastic surgery YY/T0962-2021 5.19		2026-07-28
132	Medical devices for human in vitro assisted reproductive technology-In vitro mouse embryo assay	1	All items	Medical devices for human in vitro assisted reproductive technology-In vitro mouse embryo assay YY/T 1434-2016		2026-07-28
133	Rigid gas permeable contact lenses for orthokeratology	1	All items	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016		2026-07-28
		2	Rear vertex power, column mirror power, and column mirror axis position	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.2.1		2026-07-28
		3	Transmittance performance	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.2.2		2026-07-28
		4	size	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.3		2026-07-28
		5	refractivity	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.2.1		2026-07-28
		6	oxygen permeability	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.2.2		2026-07-28
		7	hardness	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.2.3		2026-07-28
		8	contact angle	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.2.4		2026-07-28

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		№	Item/ Parameter			
		9	Mechanical	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.2.5		2026-07-28
		10	Chemical Properties	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.4.3		2026-07-28
		11	Biological evaluation	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.5		2026-07-28
		12	Microbial limit	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.6		2026-07-28
		13	stability	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.7		2026-07-28
		14	Internal quality and surface defects	Rigid gas permeable contact lenses for orthokeratology YY 0477-2016 4.8		2026-07-28
134	Phagocytosis of mouse peritoneal macrophages on chicken erythrocytes-Ex-vivo method	1	All items	Immunogenic evaluation method of medical devices-Part 4:Phagocytosis of mouse peritoneal macrophages on chicken erythrocytes-Ex-vivo method YY/T 1465.4-2017		2026-07-28
135	A method for blastocyst cell staining and counting	1	All items	Medical devices for human assisted reproductive technology-A method for blastocyst cell staining and counting YY/T 1688-2021		2026-07-28
136	Prenatal developmental toxicity test	1	All items	Test for reproductive and developmental toxicity of medical devices-Part2: Prenatal developmental toxicity test YY/T 1292.2-2015		2026-07-28
137	Cardiovascular implants— Cardiac valve	1	All items	Cardiovascular implants— Cardiac valve repair devices and delivery system YY/T 1787-2021		2026-07-28

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	repair devices and delivery system					
138	Medical devices for human assisted reproductive technology—Determination of amino acids in human assisted reproductive media	1	All items	Medical devices for human assisted reproductive technology—Determination of amino acids in human assisted reproductive media YY/T 1695-2020		2026-07-28
139	Additive manufacturing medical product—3D printing titanium alloy implant metal ion precipitation evaluation method	1	All items	Additive manufacturing medical product—3D printing titanium alloy implant metal ion precipitation evaluation method YY/T 1802-2021		2026-07-28
140	Sterilization of medical devices—Microbiological methods—Part 1:	1	All items	Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of microorganisms on products GB/T 19973.1-2015		2026-07-28

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	Determination of a population of microorganisms on products					
141	Tissue engineering medical device	1	Characterization of type I collagen	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016		2026-07-28
		2	Remnant α-Gal antigen determination	Tissue engineering medical device products-Remnant α-Gal antigen determination in scaffold materials utilizing animal tissues and their derivatives YY/T 1561-2017		2026-07-28
		3	Quantification of remnant DNA(Fluorescence method)	Tissue engineered medical product-Part 25:Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives:Fluorescence method YY/T 0606.25-2014		2026-07-28
142	Tissue engineering medical device	1	Identification	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.1		2026-07-28
		2	Purity of Type I Collagen	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.2		2026-07-28
		3	Collagen Content	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.3		2026-07-28
		4	Hydroxyproline Content	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.4		2026-07-28
		5	Peptide Profile	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.5		2026-07-28
		6	Melting Point	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.6		2026-07-28
		7	Ignition Residue	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.7		2026-07-28
		8	Total Heavy Metals and Trace Elements	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.8		2026-07-28

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		9	Acid Hydrolysis Products	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.9		2026-07-28
		10	Total Sugar Content (Calculated as Glucose)	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.10		2026-07-28
		11	Fat Content	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.11		2026-07-28
		12	Sterility, microbial limits	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.12.1		2026-07-28
		13	Bacterial endotoxins	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.12.2		2026-07-28
		14	Biological evaluation	Tissue engineering medical device products-Methods for determination of type I collagen YY/T 1453-2016 4.12.3		2026-07-28
		15	Remnant α-Gal antigen determination	Tissue engineering medical device products-Remnant α-Gal antigen determination in scaffold materials utilizing animal tissues and their derivatives YY/T 1561-2017		2026-07-28
		16	Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives:Fluorescence method	Tissue engineered medical product-Part 25:Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives:Fluorescence method YY/T 0606.25-2014		2026-07-28
143	Medical device utilizing animal tissues and their derivatives	1	immunogen	Quantification of remnant α-Gal antigen and determination of α-Gal antigen clearance in Medical devices utilizing animal tissues and their derivatives YY/T 1561-2017		2026-07-28
144	Medical devices	1	Titer of inactivated virus	Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses		2026-07-28

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	utilizing animal tissues and their derivatives or allogeneic medical device			and Transmissible Spongiform Encephalopathy(TSE) agents; YY/T 0771.3-2009		
		2	Kinetics of virus inactivited	Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and Transmissible Spongiform Encephalopathy(TSE) agents; YY/T 0771.3-2009		2026-07-28
		3	Serum immunoglobulin and complement componen	Immunogenic evaluation method of medical devices—Part 2:Serum immunoglobulin and complement component detection(enzyme-linked immunoadsordent assay) YY/T 1465.2-2016		2026-07-28
		4	Serum immunoglobulin and complement componen	Immunogenic evaluation method of medical devices—Part 2:Serum immunoglobulin and complement component detection(enzyme-linked immunoadsordent assay) YY/T 1465.2-2016		2026-07-28
		5	biomaterial-specific antibody	Tissue engineered medical products—Part 14:Standard practice for evaluation of immune responses of substrate and scaffolds products:ELISA tests YY/T 0606.14 -2014		2026-07-28
145	medical devices	1	molecular weight of collagen	Tissue engineering medical device products—Collagen protein—Part 2:Determination of molecular weight of type Ⅰ collagen—Sodium dodecyl sulfate polyacrylamide gel electrophoresis YY/T 1805.2-2021		2026-07-28
		2	Quantification of collagen based on marker peptide	Tissue engineering medical device products—Collagen protein—Part 3:quantification of collagen based on marker peptide detection-liquid chromatography-mass spectrometry YY/T 1805.3-2022		2026-07-28
		3	lymphocyte proliferation	Tissue engineered medical products—Part 15:Standard practice for evaluation of immune responses of substrate and scaffolds products:Lymphocyte proliferation tests YY/T 0606.15-2014		2026-07-28
146	Biological for nanomaterial	1	silver nanoparticles and ions released	Biological for nanomaterial medical devices—Testing and characterization methods for silver nanoparticles and ions		2026-07-28

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	medical devices—Testing and characterization methods for silver nanoparticles and ions released from silver nanoparticle containing dressing			released from silver nanoparticle containing dressing YY/T 1863-2023		
147	Fluids for haemodialysis and related therapies	1	All items	Preparation and quality management of fluids for haemodialysis and related therapies-Part 2: Water for haemodialysis and related therapies YY 0793.2-2023		2026-07-28
		2	Microbial requirements	Preparation and quality management of fluids for haemodialysis and related therapies-Part 2: Water for haemodialysis and related therapies YY 0793.2-2023 4.2		2026-07-28
		3	Chemical pollutant requirements	Preparation and quality management of fluids for haemodialysis and related therapies-Part 2: Water for haemodialysis and related therapies YY 0793.2-2023 4.3		2026-07-28
148	medical devices	1	All Parameters	Neurotoxicity evaluation of medical devices—Part 2: Tests for neuro-cytotoxicity YY/T 1670.2-2025		2026-07-28
149	Tissue-engineered medical products	1	All items	Tissue-engineered medical products. Quantification of sulfatedglycosaminoglycans （sGAG） for evaluation of chondrogenesis YY/T 1810-2022		2026-07-28
150	medical devices	1	All items	Biological evaluation of medical devices—Part 12: Sample preparation and reference materials GB/T 16886.12-2023		2026-07-28

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151	Test methods for infusion,transfusion,injection equipment for medical use	1	Pyrogen test	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 5		2026-07-28
152	infusion,transfusion,injection equipment for medical use	1	Acute systemic toxicity test	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 6		2026-07-28
153	infusion,transfusion,injection equipment for medical use	1	Hemolysis test	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 7.2		2026-07-28
154	infusion,transfusion,injection equipment for medical use	1	Coagulation test	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 7.4		2026-07-28
155	infusion,transfusion,injection equipment for medical use	1	Test of interaction between medical devices and platelets	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 7.5		2026-07-28
156	infusion,transfusion,injection equipment for medical use	1	Hematological tests	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 7.6		2026-07-28
157	infusion,transfusion,injection equipment for medical use	1	Complement activation test	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 7.7		2026-07-28

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158	infusion,transfusion,injection equipment for medical use	1	Cytotoxicity test	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 8		2026-07-28
159	infusion,transfusion,injection equipment for medical use	1	Allergen test (maximum dose method)	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 9		2026-07-28
160	infusion,transfusion,injection equipment for medical use	1	Skin reaction test	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 10		2026-07-28
161	infusion,transfusion,injection equipment for medical use	1	Post-implantation local reaction test	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 11		2026-07-28
162	infusion,transfusion,injection equipment for medical use	1	Repeated whole-body toxicity test	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 12		2026-07-28
163	infusion,transfusion,injection equipment for medical use	1	Genetic toxicity test	Test methods for infusion,transfusion,injection equipment for medical use GB/T 14233.2-2025 13		2026-07-28
164	infusion,transfusion,injection equipment for medical use	1	test for sterility	Test methods for infusion,transfusion,injection equipment for medical use—Part3:Microbiological test methods GB/T 14233.3-2024 4		2026-07-28
165	infusion,transfusion,injection	1	bacterial endotoxin test	Test methods for infusion,transfusion,injection equipment for medical use—Part3:Microbiological test methods GB/T		2026-07-28

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	equipment for medical use			14233.3-2024 5		
166	infusion,transfusion,injection equipment for medical use	1	test for bioburden	Test methods for infusion,transfusion,injection equipment for medical use—Part3:Microbiological test methods GB/T 14233.3-2024 6		2026-07-28
167	infusion,transfusion,injection equipment for medical use	1	test for sterility	Test methods for infusion,transfusion,injection equipment for medical use—Part3:Microbiological test methods GB/T 14233.3-2024 7		2026-07-28
168	Recombinant collagen protein	1	Partial items	Recombinant collagen protein YY/T 1849-2022	Except for visible foreign matter,solubility,moisture content,dynamic viscosity,thermal stability,Terminal amino acid sequence (amino acid sequence analyzer method),isoelectric point,Residual	2026-07-28

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					antibiotic content/activity(HPLC-MS),Content of heavy metals and trace elements(Atomic absorption spectrophotometry),additive,Content (characteristic polypeptide method),Characterization of primary structure (amino acid sequence analyzer method),IR,CD,Microcalorimetric analysis,Protein sensitivity	

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					analysis,Glycofile/glycosylation modification analysis,cell proliferation,cell differentiation and stability	
		2	Appearance	Recombinant collagen protein YY/T 1849-2022 5.2.1		2026-07-28
		3	Residue on ignition	Recombinant collagen protein YY/T 1849-2022 5.2.5		2026-07-28
		4	pH	Recombinant collagen protein YY/T 1849-2022 5.2.6		2026-07-28
		5	Determination of osmolality	Recombinant collagen protein YY/T 1849-2022 5.2.7		2026-07-28
		6	Test for minimum filling and Content uniformity	Recombinant collagen protein YY/T 1849-2022 5.2.10		2026-07-28
		7	Paptide Mapping Analysis	Recombinant collagen protein YY/T 1849-2022 5.3.1		2026-07-28
		8	Terminal amino acid sequence	Recombinant collagen protein YY/T 1849-2022 5.3.2		2026-07-28
		9	Protein molecular weight	Recombinant collagen protein YY/T 1849-2022 5.3.3		2026-07-28
		10	SDS PAGE （Protein purity）	Recombinant collagen protein YY/T 1849-2022 5.4.1		2026-07-28

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		11	HPLC method （Protein purity）	Recombinant collagen protein YY/T 1849-2022 5.4.2		2026-07-28
		12	Exogenous DNA residue (fluorescence staining method)	Recombinant collagen protein YY/T 1849-2022 5.5.2		2026-07-28
		13	Residual protein content of Escherichia coli	Recombinant collagen protein YY/T 1849-2022 5.5.3		2026-07-28
		14	Yeast protein residue	Recombinant collagen protein YY/T 1849-2022 5.5.4		2026-07-28
		15	Residual protein content in CHO cells	Recombinant collagen protein YY/T 1849-2022 5.5.5		2026-07-28
		16	Residual antibiotic content (enzyme-linked immunosorbent assay)	Recombinant collagen protein YY/T 1849-2022 5.5.6		2026-07-28
		17	Inflammatory pollutants (peptidoglycans, etc.)	Recombinant collagen protein YY/T 1849-2022 5.5.7		2026-07-28
		18	Content of heavy metals and trace elements	Recombinant collagen protein YY/T 1849-2022 5.5.8		2026-07-28
		19	Protein content	Recombinant collagen protein YY/T 1849-2022 5.6.1		2026-07-28
		20	Heterogeneity Analysis	Recombinant collagen protein YY/T 1849-2022 5.7.1		2026-07-28

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		21	Analysis of amino acid	Recombinant collagen protein YY/T 1849-2022 5.7.2		2026-07-28
		22	Proline Hydroxylation Analysis	Recombinant collagen protein YY/T 1849-2022 5.7.7		2026-07-28
		23	Cell adhesion	Recombinant collagen protein YY/T 1849-2022 5.8.4		2026-07-28
		24	Cell migration	Recombinant collagen protein YY/T 1849-2022 5.8.5		2026-07-28
		25	sterile	Recombinant collagen protein YY/T 1849-2022 5.9.2		2026-07-28
		26	bacterial endotoxin	Recombinant collagen protein YY/T 1849-2022 5.9.3		2026-07-28
		27	Microbial Limit	Recombinant collagen protein YY/T 1849-2022 5.9.4		2026-07-28
		28	Biological Evaluation	Recombinant collagen protein YY/T 1849-2022 7		2026-07-28
		29	All items	Peptide mass fingerprinting analysis of recombinant collagen YY/T 1954-2025		2026-07-28
		30	Paptide Mapping Analysis	Peptide mass fingerprinting analysis of recombinant collagen YY/T 1954-2025 8.1		2026-07-28
		31	Peptide coverage	Peptide mass fingerprinting analysis of recombinant collagen YY/T 1954-2025 8.2		2026-07-28
		32	Heterogeneity Analysis	Peptide mass fingerprinting analysis of recombinant collagen YY/T 1954-2025 8.3		2026-07-28
169	Ophthalmic optics-Intraocular lenses	1	Partial items	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023	Except for Intraocular implantation	2026-07-28
		2	Ultimate leaching test	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023 5.3		2026-07-28

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		3	Leachable substance test	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023 5.4		2026-07-28
		4	Hydrolysis Stability Test	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023 5.5		2026-07-28
		5	Light stability test	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023 5.6		2026-07-28
		6	Nd-YAG laser irradiation test	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023 5.7		2026-07-28
		7	Evaluation of insoluble inorganic matter	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023 5.8		2026-07-28
		8	Tests for in vitro cytotoxicity	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023 6.2		2026-07-28
		9	Tests For skin sensitization	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023 6.3		2026-07-28
		10	Tests for genotoxicity	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023 6.4		2026-07-28
		11	Tests for local effects after implantation	Ophthalmic optics-Intraocular lenses-Part 5:Biocompatibility YY/T 0290.5-2023 6.5		2026-07-28
170	Cardiovascular implants-Cardiac valve prostheses	1	All items	Cardiovascular implants- Cardiac valve prostheses-Part1: General requirements GB/T12279.1-2024		2026-07-28
		2	Material property assessment	Cardiovascular implants- Cardiac valve prostheses-Part1: General requirements GB/T12279.1-2024 7.2.3		2026-07-28
		3	Hydrodynamic performance assessment	Cardiovascular implants- Cardiac valve prostheses-Part1: General requirements GB/T12279.1-2024 7.2.4		2026-07-28
		4	Structural performance assessment	Cardiovascular implants- Cardiac valve prostheses-Part1: General requirements GB/T12279.1-2024 7.2.5		2026-07-28

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		5	Design- or procedure-specific testing	Cardiovascular implants- Cardiac valve prostheses-Part1: General requirements GB/T12279.1-2024 7.2.6		2026-07-28
		6	Simulated use	Cardiovascular implants- Cardiac valve prostheses-Part1: General requirements GB/T12279.1-2024 7.2.8		2026-07-28
		7	Human factors/usability assessment	Cardiovascular implants- Cardiac valve prostheses-Part1: General requirements GB/T12279.1-2024 7.2.9		2026-07-28
		8	Implant thrombogenic and haemolytic potential assessment.	Cardiovascular implants- Cardiac valve prostheses-Part1: General requirements GB/T12279.1-2024 7.2.10		2026-07-28
		9	All items	Cardiovascular implants- Cardiac valve prostheses-Part2: Surgically implanted heart valve substitutes GB/T12279.2-2024		2026-07-28
		10	Material property assessment	Cardiovascular implants- Cardiac valve prostheses-Part2: Surgically implanted heart valve substitutes GB/T12279.2-2024 7.2.3		2026-07-28
		11	Hydrodynamic performance assessment	Cardiovascular implants- Cardiac valve prostheses-Part2: Surgically implanted heart valve substitutes GB/T12279.2-2024 7.2.4		2026-07-28
		12	Structural performance assessment	Cardiovascular implants- Cardiac valve prostheses-Part2: Surgically implanted heart valve substitutes GB/T12279.2-2024 7.2.5		2026-07-28
		13	Design- or procedure-specific testing	Cardiovascular implants- Cardiac valve prostheses-Part2: Surgically implanted heart valve substitutes GB/T12279.2-2024 7.2.6		2026-07-28
		14	Simulated use	Cardiovascular implants- Cardiac valve prostheses-Part2: Surgically implanted heart valve substitutes GB/T12279.2-2024 7.2.8		2026-07-28

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		15	Human factors/usability assessment	Cardiovascular implants- Cardiac valve prostheses-Part2: Surgically implanted heart valve substitutes GB/T12279.2-2024 7.2.9		2026-07-28
		16	Implant thrombogenic and haemolytic potential assessment.	Cardiovascular implants- Cardiac valve prostheses-Part2: Surgically implanted heart valve substitutes GB/T12279.2-2024 7.2.10		2026-07-28
		17	All items	Cardiovascular implants- Cardiac valve prostheses-Part3: Heart valve substitutes implanted by transcatheter techniques GB/T12279.3-2025		2026-07-28
		18	Material property assessment	Cardiovascular implants- Cardiac valve prostheses-Part3: Heart valve substitutes implanted by transcatheter techniques GB/T12279.3-2025 7.2.3		2026-07-28
		19	Hydrodynamic performance assessment	Cardiovascular implants- Cardiac valve prostheses-Part3: Heart valve substitutes implanted by transcatheter techniques GB/T12279.3-2025 7.2.4		2026-07-28
		20	Structural performance assessment	Cardiovascular implants- Cardiac valve prostheses-Part3: Heart valve substitutes implanted by transcatheter techniques GB/T12279.3-2025 7.2.5		2026-07-28
		21	Design- or procedure-specific testing	Cardiovascular implants- Cardiac valve prostheses-Part3: Heart valve substitutes implanted by transcatheter techniques GB/T12279.3-2025 7.2.6		2026-07-28
		22	Simulated use	Cardiovascular implants- Cardiac valve prostheses-Part3: Heart valve substitutes implanted by transcatheter techniques GB/T12279.3-2025 7.2.8		2026-07-28
		23	Human factors and usability assessment	Cardiovascular implants- Cardiac valve prostheses-Part3: Heart valve substitutes implanted by transcatheter techniques GB/T12279.3-2025 7.2.9		2026-07-28
		24	Implant thrombogenic and	Cardiovascular implants- Cardiac valve prostheses-Part3: Heart valve substitutes implanted by transcatheter techniques		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			haemolytic potential assessment.	GB/T12279.3-2025 7.2.10		
171	Cardiovascular implants—Cardiovascular absorbableimplants	1	All items	Cardiovascular implants—Cardiovascular absorbableimplants GB/T44138—2024		2026-07-28
		2	In vitro evaluation	Cardiovascular implants—Cardiovascular absorbableimplants GB/T44138—2024 5.2		2026-07-28
		3	In vitro degradation assessment	Cardiovascular implants—Cardiovascular absorbableimplants GB/T44138—2024 5.3		2026-07-28
		4	Biocompatibility	Cardiovascular implants—Cardiovascular absorbableimplants GB/T44138—2024 5.4		2026-07-28
172	Small-bore connectors for liquids and gases in healthcare applications	1	All items	Small-bore connectors for liquids and gases in healthcare applications-Part 7:Connectors for intravascular or hypodermic applications YY/T 0916.7-2024		2026-07-28
		2	Fluid leakage requirements	Small-bore connectors for liquids and gases in healthcare applications-Part 7:Connectors for intravascular or hypodermic applications YY/T 0916.7-2024 6.1.1		2026-07-28
		3	Pressure attenuation leakage	Small-bore connectors for liquids and gases in healthcare applications-Part 7:Connectors for intravascular or hypodermic applications YY/T 0916.7-2024 6.1.2		2026-07-28
		4	Positive pressure liquid leakage	Small-bore connectors for liquids and gases in healthcare applications-Part 7:Connectors for intravascular or hypodermic applications YY/T 0916.7-2024 6.1.3		2026-07-28
		5	Negative pressure air leakage	Small-bore connectors for liquids and gases in healthcare applications-Part 7:Connectors for intravascular or hypodermic applications YY/T 0916.7-2024 6.2		2026-07-28
		6	Stress cracking	Small-bore connectors for liquids and gases in healthcare applications-Part 7:Connectors for intravascular or hypodermic applications YY/T 0916.7-2024 6.3		2026-07-28
		7	Anti axial load separation	Small-bore connectors for liquids and gases in healthcare applications-Part 7:Connectors for intravascular or hypodermic		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				applications YY/T 0916.7-2024 6.4		
		8	Anti rotation torque separation	Small-bore connectors for liquids and gases in healthcare applications-Part 7:Connectors for intravascular or hypodermic applications YY/T 0916.7-2024 6.5		2026-07-28
		9	Anti overload (sliding wire)	Small-bore connectors for liquids and gases in healthcare applications-Part 7:Connectors for intravascular or hypodermic applications YY/T 0916.7-2024 6.6		2026-07-28
		10	Partial items	Small-bore connectors for liquids and gases in healthcare applications Part 20:Common test methods YY/T 0916.20-2019	Except the unscrew separation test method	2026-07-28
		11	Pressure decay leakage test method	Small-bore connectors for liquids and gases in healthcare applicationsPart 20:Common test methods YY/T 0916.20-2019 Appendix B		2026-07-28
		12	Positive pressure liquid dripping leakage test method	Small-bore connectors for liquids and gases in healthcare applicationsPart 20:Common test methods YY/T 0916.20-2019 Appendix C		2026-07-28
		13	Negative pressure air leakage test method	Small-bore connectors for liquids and gases in healthcare applicationsPart 20:Common test methods YY/T 0916.20-2019 Appendix D		2026-07-28
		14	Stress cracking test method	Small-bore connectors for liquids and gases in healthcare applicationsPart 20:Common test methods YY/T 0916.20-2019 Appendix E		2026-07-28
		15	Anti-axial load separation test method	Small-bore connectors for liquids and gases in healthcare applicationsPart 20:Common test methods YY/T 0916.20-2019 Appendix F		2026-07-28
		16	Anti-unscrewing torque separation test method	Small-bore connectors for liquids and gases in healthcare applicationsPart 20:Common test methods YY/T 0916.20-2019 Appendix G		2026-07-28

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		17	Anti overload (sliding wire)	Small-bore connectors for liquids and gases in healthcare applications Part 20:Common test methods YY/T 0916.20-2019 Appendix H		2026-07-28
173	Fluid lines for use with pressure infusion equipment and accessories for single use	1	Partial items	Fluid lines for use with pressure infusion equipment and accessories for single use-Part 4:Check valves YY 0585.4-2024	Only reflux pressure impedance ,blocking performanc e,chemical requiremen ts and biological requiremen ts	2026-07-28
		2	Reflux pressure impedance	Fluid lines for use with pressure infusion equipment and accessories for single use-Part 4:Check valves YY 0585.4-2024 6.4		2026-07-28
		3	Blocking performance	Fluid lines for use with pressure infusion equipment and accessories for single use-Part 4:Check valves YY 0585.4-2024 6.6		2026-07-28
		4	Chemical requirements	Fluid lines for use with pressure infusion equipment and accessories for single use-Part 4:Check valves YY 0585.4-2024 7		2026-07-28
		5	Sterility	Fluid lines for use with pressure infusion equipment and accessories for single use-Part 4:Check valves YY 0585.4-2024 8.2		2026-07-28
		6	Pyrogen	Fluid lines for use with pressure infusion equipment and accessories for single use-Part 4:Check valves YY 0585.4-2024 8.3		2026-07-28
174	medical devices	1	molecular weight of collagen	Tissue engineering medical device products—Collagen protein—Part 2:Determination of molecular weight of type Ⅰ collagen—		2026-07-28

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		№	Item/ Parameter			
				Sodium dodecyl sulfate polyacrylamide gel electrophoresis YY/T 1805.2-2021		
		2	Quantification of collagen based on marker peptide	Tissue engineering medical device products—Collagen protein—Part 3:quantification of collagen based on marker peptide detection-liquid chromatography-mass spectrometry YY/T 1805.3-2022		2026-07-28
		3	Quantification of remnant DNA	Tissue engineered medical products-Quantification of remnant DNA in biological materials utilizing animal tissues and their derivatives: Fluorescence method YY/T 1876-2023		2026-07-28
Active medical device						
1	Medical electrical equipment	1	All items	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020		2026-07-28
		2	General requirements	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.1		2026-07-28
		3	secondary tip vibration excursion	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.2		2026-07-28
		4	drive frequency	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.3		2026-07-28
		5	drived output acoustic power	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.4		2026-07-28
		6	quiescent electrical power	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.5		2026-07-28
		7	maximum electrical power	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.6		2026-07-28
		8	clamping force	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.7		2026-07-28
		9	grasping force	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.8		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	Appearance and structure	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.9		2026-07-28
		11	power supply	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.10		2026-07-28
		12	power input	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 4.11		2026-07-28
		13	type tests	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.1		2026-07-28
		14	ambient temperature,humidity,atmospheric pressure	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.3		2026-07-28
		15	supply voltage,type of current,nature of supply,frequency	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.5		2026-07-28
		16	humidity preconditioning treatment	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.7		2026-07-28
		17	determination of applied parts and accessible parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 5.9		2026-07-28
		18	protection against electric shock	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.2		2026-07-28
		19	protection against harmful ingress of water or particulate matter	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.3		2026-07-28
		20	methods of sterilization	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.4		2026-07-28

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SCHEDULE OF ACCREDITED TESTS

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		21	suitability for use in oxygen rich environment	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.5		2026-07-28
		22	mode of operation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 6.6		2026-07-28
		23	General	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.1		2026-07-28
		24	marking on the outside of ME EQUITMENT or ME EQUITMENT parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.2		2026-07-28
		25	marking on the inside of ME EQUITMENT or ME EQUITMENT parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.3		2026-07-28
		26	markings of controls and instruments	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.4		2026-07-28
		27	safety signs	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.5		2026-07-28
		28	symbols	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.6		2026-07-28
		29	colours of the insulation of conductors	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.7		2026-07-28
		30	indicator lights and controls	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.8		2026-07-28
		31	accompanying documents	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 7.9		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		32	Fundamental rule of protection against electric shock	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.1		2026-07-28
		33	Requirements related to power sources	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.2		2026-07-28
		34	Classification of APPLIED PARTS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.3		2026-07-28
		35	Limitation of voltage, current or energy	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.4		2026-07-28
		36	Separation of parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.5		2026-07-28
		37	Protective earthing, functional earthing and potential equalization ofME EQUIPMENT	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.6		2026-07-28
		38	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.7		2026-07-28
		39	Insulation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.8		2026-07-28
		40	CREEPAGE DISTANCES and AIR CLEARANCES	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.9		2026-07-28

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		41	Components and wiring	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.10		2026-07-28
		42	MAINS PARTS, components and layout	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 8.11		2026-07-28
		43	HAZARDS associated with moving parts	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.2		2026-07-28
		44	HAZARD associated with surfaces, corners and edges	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.3		2026-07-28
		45	Instability HAZARDS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.4		2026-07-28
		46	Expelled parts HAZARD	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.5		2026-07-28
		47	Acoustic energy (including infra- and ultrasound) and vibration	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.6		2026-07-28
		48	Pressure vessels and parts subject to pneumatic and hydraulic pressure..... 285	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.7		2026-07-28
		49	HAZARDS associated with support systems	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 9.8		2026-07-28
		50	X-Radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.1		2026-07-28

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		№	Item/ Parameter			
		51	Alpha, beta, gamma, neutron and other particle radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.2		2026-07-28
		52	Microwave radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.3		2026-07-28
		53	Lasers	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.4		2026-07-28
		54	Other visible electromagnetic radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.5		2026-07-28
		55	Infrared radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.6		2026-07-28
		56	Ultraviolet radiation	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 10.7		2026-07-28
		57	Excessive temperatures in ME EQUIPMENT.	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.1		2026-07-28
		58	Fire prevention	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.2		2026-07-28
		59	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT .	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.3		2026-07-28
		60	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics.	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.4		2026-07-28
		61	ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.5		2026-07-28

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		№	Item/ Parameter			
			intended for use in conjunction with flammable agents			
		62	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning,disinfection, sterilization and compatibility with substances used with theME EQUIPMENT...	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.6		2026-07-28
		63	Interruption of the power supply SUPPLY MAINS to ME EQUIPMENT	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 11.8		2026-07-28
		64	Accuracy of controls and instruments	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.1		2026-07-28
		65	USABILITY	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.2		2026-07-28
		66	Alarm systems	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.3		2026-07-28
		67	Protection against hazardous output....	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 12.4		2026-07-28
		68	Specific HAZARDOUS SITUATIONS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 13.1		2026-07-28

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		69	SINGLE FAULT CONDITIONS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 13.2		2026-07-28
		70	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 14		2026-07-28
		71	Arrangements of controls and indicators of ME EQUIPMENT	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.1		2026-07-28
		72	Serviceability	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.2		2026-07-28
		73	Mechanical strength	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.3		2026-07-28
		74	ME EQUIPMENT components and general assembly	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.4		2026-07-28
		75	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 15.5		2026-07-28
		76	General requirements for the ME SYSTEMS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.1		2026-07-28
		77	ACCOMPANYING DOCUMENTS of	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.2		2026-07-28

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ANNEX TO SCHEDULE OF ACCREDITATION CERTIFICATE

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			an ME SYSTEM			
		78	Power supply .	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.3		2026-07-28
		79	ENCLOSURES	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.4		2026-07-28
		80	SEPARATION DEVICES.....	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.5		2026-07-28
		81	LEAKAGE CURRENTS.	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.6		2026-07-28
		82	Protection against MECHANICAL HAZARDS	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.7		2026-07-28
		83	Interruption of the power supply to parts of an ME SYSTEM	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.8		2026-07-28
		84	ME SYSTEM connections and wiring	Medical electrical equipment Part 1: General requirements for the basic safety and essential performance GB 9706.1-2020 16.9		2026-07-28
		85	All items	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021		2026-07-28
		86	General requipment	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		87	ME EQUIPMENT indentification marking and documents	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 5		2026-07-28
		88		Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 5.1		2026-07-28
		89	ACCOMPANYING DOCUMENTS	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 5.2		2026-07-28
		90	ALARM CONTION	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.1		2026-07-28
		91	Disclosures for INTELLIGENT ALARM SYSTEM	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.2		2026-07-28
		92	Generation of ALARM SIGNALS	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.3		
		93	Disclosure of delays	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.4		2026-07-28
		94	ALARM PRESETS	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.5		2026-07-28
		95	ALARM LIMIT	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.6		2026-07-28
		96	ALARM SYSTEM security	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.7		2026-07-28
		97	ALARM SIGNAL inactivation states	Medical electrical equipment-Part1-8：General requipments for basic safety and essential performance-Collateral standard：General requirement，tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.8		2026-07-28
		98	ALARM RESET	Medical electrical equipment-Part1-8：General requipments for		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.9		
		99	NON-LATCHING and LATCHING ALARM SIGNALS	Medical electrical equipment-Part1-8: General requipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.10		2026-07-28
		100	DISTRIBUTED ALARM SYSTEM	Medical electrical equipment-Part1-8: General requipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.11		2026-07-28
		101	ALARM SYSTEM logging	Medical electrical equipment-Part1-8: General requipments for basic safety and essential performance-Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY/T 9706.108-2021 6.12		2026-07-28
		102	All items	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020		2026-07-28
		103	environmental requirement	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 4.1		2026-07-28
		104	Testing equipment requirements	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 4.2		2026-07-28
		105	Preparation requirements before testing	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 4..3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		106	shutdown mode	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 5.1		2026-07-28
		107	standby mode	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 5.2		2026-07-28
		108	Operating mode	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 5.3		2026-07-28
		109	low power mode	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 5.4		2026-07-28
		110	charge mode	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 5.5		2026-07-28
		111	energy consumption calculation	Measurement method for energy consumption of medical electrical equipment YY/T 1738-2020 6		2026-07-28
		112	Partial items	Medical electrical equipment Part1:General requirements for safety GB 9706.1-2007	Except for 39-41；For use only when referenced or as stipulated in special contracts	2026-07-28
				Medical electrical equipment Part1:General requirements for safety IEC 60601-1：2005+A1:2012+A2:2020	Except for 39-41	2026-07-28
				Medical electrical equipment Part1:General requirements for safety IEC 60601-1:1988	Except for 39-41,For use only when referenced or as stipulated	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					in special contracts	
		113	All items	Medical electrical equipment Part1:General requirements for safety-1.Collateral standard:Safety requirements for medical electrical systems GB 9706.15-2008	For use only when referenced or as stipulated in special contracts	2026-07-28
		114	All items	The environmental requirements and test methods for medical electrical equipment GB/T 14710-2009		2026-07-28
		115	All items	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023		2026-07-28
		116	General requirements	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 4.1		2026-07-28
		117	Testing before delivery, after modification, and after repair	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 4.2		2026-07-28
		118	periodic testing	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 4..3		2026-07-28
		119	overview	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 5.1		2026-07-28
		120	visual inspection	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 5.2		2026-07-28
		121	measure	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 5.3		2026-07-28
		122	functional testing	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 5.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		123	test report	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 6.1		2026-07-28
		124	energy consumption calculation	Medical electrical equipment-Recurrent test and test after repair of medical electrical equipment YY/T 0841-2023 6.2		2026-07-28
		125	All items	Medical electrical equipment-Part 1-8:General requirements for safety-Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems YY 0709-2009	For use only when referenced or as stipulated in special contracts	2026-07-28
				Medical electrical equipment-Part 1-8: General requirements for basic safety and essential performance-Collateral standard: General requirements,tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8:2006+A1:2012+A2:2020		2026-07-28
		126	All items	Electric apparatus for gastric lavage YY 1105-2008		2026-07-28
		127	All items	General Specificationgs for medical foot switch YY/T 1057-2016		2026-07-28
		128	All items	fire hazard testing for electric and electronic products-part21:abnormal heat-ball pressure test GB/T 5169.21-2017		2026-07-28
		129	All items	Flammability of solid non-metallic meterials when exposed to flame sources-list of test methods GB/T 11020-2005	For use only when referenced or as stipulated in special contracts	2026-07-28
		130	All items	Method for determining the comparative and the proof trackin indices of solid insulating materials under moist conditionis GB/T		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				4207-2022		
		131	All items	fire hazard testing for electric and electronic products—part16:test flames—50W horizontal and vertical flame test methods GB/T 5169.16-2017		2026-07-28
		132	All items	Medical electrical equipment—Part 1-10: General requirements for basic safety and essential performance-Collateral Standard: Requirements for the development of physiologic closed-loop controlllers YY/T 9706.110-2021		2026-07-28
		133	All items	Medical electrical equipment-Part 2: Padicular requirements for the safet y ofexternal cardiac pacemakers with internal power source YY 0945.2- 2015		2026-07-28
2	Medical electrical equipment intended for use in the emergency medical services environment	1	All items	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021		2026-07-28
		2	Additional requirements for ME equipment and the power grid of ME systems	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 4.1		2026-07-28
		3	Environmental conditions of ME equipment	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 4.2		2026-07-28
		4	Classification of ME equipment and ME systems	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				medical services envi YY 9706.112-2021 5		
		5	Additional requirements for legibility of marks	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 6.1		2026-07-28
		6	Additional requirements for IP classification marking	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 6.2		2026-07-28
		7	Operating manual	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 6.3		2026-07-28
		8	Technical manual：Fixed or permanently installed class I ME equipment	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 6.4		2026-07-28
		9	Protection of electrical hazard (source) of ME equipment	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 7		2026-07-28
		10	Additional requirements for water or particulate	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			matter intrusion into ME equipment and ME systems	medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 8.1		
		11	Additional requirements for power supply/grid interruptions for ME equipment and ME systems	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 8.2		2026-07-28
		12	Additional requirements for internal power supply of ME equipment	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 8.3		2026-07-28
		13	Controller and meter accuracy and hazard output protection	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 9		2026-07-28
		14	Additional mechanical strength requirements for ME equipment intended for use in EMS environments	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 10.1		2026-07-28
		15	Requirements for installation of ME equipment	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 10.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Additional requirements for EMC of ME equipment and ME systems	Medical electrical equipment-Part 1-12:General requirements for basic safety and essential performance-Collateral Standard:Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services envi YY 9706.112-2021 11		2026-07-28
3	Medical electrical equipment used in the home healthcare environment	1	All items	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021		2026-07-28
		2	Additional requirements for supply mains for ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 4.1		2026-07-28
		3	Environmental conditions for transport and storage between uses	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 4.2.2		2026-07-28
		4	Environmental operating conditions	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 4.2.3.1		2026-07-28
		5	Environmental shock to Transit-operable ME equipment	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 4.2.3.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		6	General requirments for testing ME equipment	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 5		2026-07-28
		7	classification of ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 6		2026-07-28
		8	usability of the accompanying documents	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.1		2026-07-28
		9	additional requirements for marking of IP classification	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.2		2026-07-28
		10	accompanying documents	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.3		2026-07-28
		11	instructions for use	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	technical description	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 7.5		2026-07-28
		13	additional requirments for cleaning ,disinfection of ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.1		2026-07-28
		14	additional requirements for sterilization of ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.2		2026-07-28
		15	additional requirements for ingress of water or particulate matter into ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.3		2026-07-28
		16	additional requirements for interruption of the power supply/supply mains to ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.4		2026-07-28
		17	Status indication	Medical electrical equipment Part 1-11: General requirements for		2026-07-28

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		№	Item/ Parameter			
				the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.5.1		
		18	Accessibility of small internal power supply	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 8.5.2		2026-07-28
		19	accuracy of ocntrols and instruments and portection against hazardous outputs	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 9		2026-07-28
		20	requirements for mechanical strength for non-transit-operable ME equipment	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 10.1.2		2026-07-28
		21	requirements for mechanical strength for transit-operable ME equipment	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 10.1.3		2026-07-28
		22	additonal requirements for actuating parts of controls of ME equipment	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 10.2		2026-07-28
		23	protection against	Medical electrical equipment Part 1-11: General requirements for		2026-07-28

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			strangulation or asphyxiation	the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 11		
		24	additional requirements for electromagnetic compatibility of ME equipment and ME systems	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 12		2026-07-28
		25	additional requirements for generation of alarm signals	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 13.1		2026-07-28
		26	additional requirements for alarm signal volume	Medical electrical equipment Part 1-11: General requirements for the basic safety and essential performance -Collateral standard:requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment YY 9706.111-2021 13.2		2026-07-28
4	Monitoring equipment	1	All items	Medical electrical equipment part2:particular requirements for the safety of electrocardiographic monitoring equipment GB 9706.25-2005	For use only when referenced or as stipulated in special contracts	2026-07-28
				Medical electrical equipment part2:particular requirements for the safety of electrocardiographic monitoring equipment IEC 60601-2-27:1994		2026-07-28

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		2	All items	Medical electrical equipment-Particular requirements for basic safety and essential performance of respiratory gas monitors YY 0601-2010	For use only when referenced or as stipulated in special contracts	2026-07-28
		3	All items	ECG cables and leadwires YY 0828-2011/XG1-2025		2026-07-28
		4	All items	Medical electrical equipment- Part 2-27 :Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment GB 9706.227-2021		2026-07-28
5	Physiological parameters analysis and measurement equipment	1	All items	Medical electrical equipment—— Part 2-34：Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipments YY 0783-2010	For use only when referenced or as stipulated in special contracts	2026-07-28
		2	All items	Medical electrical equipment—part2-30:particular requirements for the safety,including essential performance,of automatic cycling non-invasive blood pressure monitoring equipment YY 0667-2008	For use only when referenced or as stipulated in special contracts	2026-07-28
		3	All items	Clinical electronic thermometer GB/T 21416-2008/XG1-2008		2026-07-28
		4	All items	Clinical thermometers—Performance of electrical thermometers for continuous measurement YY 0785-2010		2026-07-28

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		5	Partial items	Clinical infrared thermometers— Part 1 :Ear GB/T 21417.1-2008	except for 4.4.4	2026-07-28
		6	All items	Temperature biofeedback equipment YY/T 1096-2007		2026-07-28
		7	All items	Bridge type impedance blood flow recorder YY/T 1143-2008		2026-07-28
		8	All items	Direct impedance blood flow recorder YY/T 1078-2008		2026-07-28
		9	All items	Myoelectric biofeedback equipment YY/T 1095-2015		2026-07-28
		10	All items	Electroencephalographic biofeedback equipment YY 0903-2013		2026-07-28
		11	All items	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs GB 9706.226-2021		2026-07-28
		12	All items	Medical Electrical Equipment – Part 2-40: Particular Requirements For The Basic Safety And Essential Performance Of Electromyographs And Evoked Response Equipment YY 9706.240-2021		2026-07-28
		13	All items	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment YY 9706.234-2021		2026-07-28
		14	All items	Medical electrical equipment—part2-30:particular requirements for the basic safety and essential performanceof automated non-invasive sphygmomanometers YY9706.230-2023		2026-07-28
		15	All items	Medical Electrical equipment—Part 2-61:Particular requirements for the basic safety and essential performance of pulse oximeter equipement YY 9706.261-2023		2026-07-28
		16	All items	MedicaI eIectricaI equipment-Part2-49：ParticuIar requirements for the basic safety and essentiaI performance of muItifunction patient monitors YY 9706.249-2023		2026-07-28

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		17	All items	Electrophysiology catheter YY/T 1519-2017		2026-07-28
		18	All items	Multi-channels electrophysiology recording system YY/T 1635-2018		2026-07-28
		19	All items	Electrical pneumatic touriquet equipment YY/T 1830-2022		2026-07-28
		20	All items	Stethoscope YY/T 1035-2021		2026-07-28
		21	Appearance and structural requirements	Stethoscope YY/T 1035-2021 4.1		2026-07-28
		22	stethoscopesound transmission performance	Stethoscope YY/T 1035-2021 4.2		2026-07-28
		23	Requirements for stethoscope earrings	Stethoscope YY/T 1035-2021 4.3		2026-07-28
		24	Requirements for sound transmission connection conduit	Stethoscope YY/T 1035-2021 4.4		2026-07-28
6	electrocardiograph	1	All items	single and multichannel electrocardiograph YY 1139-2013		2026-07-28
		2	All items	Medical electrical equipment-part 2：Particular requirements for the safety,including essential performance of ambulatory electrocardiographic systems YY 0885-2013	For use only when referenced or as stipulated in special contracts	2026-07-28
		3	All items	Disposable ECG electrodes YY/T 0196-2005		2026-07-28

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		№	Item/ Parameter			
		4	All items	Medical electrical equipment-Part 2-47:Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems YY 9706.247-2021		2026-07-28
		5	All items	Medical electrical equipment-Part 2-25:Particular requirements for the basic safety and essential performance of electrocardiographs GB 9706.225-2021		2026-07-28
7	Optical equipment and appliances	1	All items	ophthalmic instruments-Trial case lenses GB/T 17342-2009		2026-07-28
		2	All items	Opthalmic instruments-Perimeters YY/T 0676-2008/XGI-2021		2026-07-28
		3	All items	ophthalmic instruments-Refractor heads YY 0674-2008		2026-07-28
		4	All items	Ophthalmic instruments-Fundus camera YY 0634-2022		2026-07-28
				Ophthalmic instruments-Fundus camera ISO 10940:2009		2026-07-28
		5	All items	Ophthalmic instruments-Endoilluminators-Part 1: Requirements and test methods YY 0792.1-2016		2026-07-28
		6	All items	Ophthalmic instruments-Endoilluminators-Part 2:Fundamental requirements and test methods for optical radiation safety YY 0792.2-2010		2026-07-28
		7	All items	Ophthalmic optics and instruments-Optical devices for enhancing low vision GB 23719-2009		2026-07-28
		8	All items	Opthalmic instruments—Synoptophores YY/T 0675-2008	For use only when referenced or as stipulated in special contracts	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Opthalmic instruments—Synoptophores ISO 10944:2009		2026-07-28
		9	All items	Opthalmic instruments-Eye refractometers YY 0673-2008		2026-07-28
		10	All items	Ophthalmic instruments — Fundamentalrequirements and test methods —Part 1:General requirements applicableto all ophthalmic instruments ISO15004-1：2020		2026-07-28
		11	All items	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024		2026-07-28
		12	All items	Ophthalmic instruments-Microkeratome YYT/T 0788-2010		2026-07-28
		13	All items	standard for logarithmic visual acuity charts GB/T 11533-2011		2026-07-28
		14	All items	Measurement methods of illuminance for medical optical instruments YY/T 1146-2016		2026-07-28
		15	All items	pupil distance meters JJG 952-2014		2026-07-28
		16	Partial items	Assembled spectacles—Part 1: Single-vision and multifocal prescription assembled spectacles GB/T13511.1-2025	except5.4	2026-07-28
		17	All items	Optics and optical instruments—Focimeters GB /T 17341-1998		2026-07-28
		18	All items	Ophthalmometers GB 38455-2019		2026-07-28
				Ophthalmometers ISO 10343:2014		2026-07-28
		19	All items	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024		2026-07-28
		20	General	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 4.1		2026-07-28
		21	Group 1 instruments	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 4.2		2026-07-28

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		№	Item/ Parameter			
		22	Group 2 instruments	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 4.3		2026-07-28
		23	General	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 5.1		2026-07-28
		24	Requirements for classification as a Group 1 instrument	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 5.2		2026-07-28
		25	Requirements for classification as a Group 2 instrument	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 5.3		2026-07-28
		26	Exposure limits for Group 1 classification	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 5.4		2026-07-28
		27	Recommended maximum exposure (RME) values for Group 2 instruments	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 5.5		2026-07-28
		28	Exposure limits and maximum recommended exposure values	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 5.6		2026-07-28
		29	Group 2 instruments: determination of time and number of pulses to reach recommended maximum exposure	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 6.4		2026-07-28
		30	Information supplied by the	Ophthalmic instruments-Fundamental requirements and test methods-Part 2：Light hazard protection ISO 15004-2：2024 7		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			manufacturer			
8	Ophthalmic measurement diagnostic equipment and apparatus	1	All items	Opthalmic instruments-Retinoscopes YY/T 0718-2009/XG1-2023		2026-07-28
		2	All items	Ophthalmic instruments-Direct ophthalmoscopes YY/T 1080-2009/XG1-2024		2026-07-28
		3	All items	Ophthalmic instruments- Indirect ophthalmoscope YY/T 0633-2022		2026-07-28
				Ophthalmic instruments- Indirect ophthalmoscope ISO 10943:2023		2026-07-28
		4	All items	Opthalmic instruments—Corneal topographers YY/T 0787-2024		2026-07-28
		5	Area measured	Opthalmic instruments—Corneal topographers YY/T 0787-2024 4.1		2026-07-28
		6	Measurement sample density	Opthalmic instruments—Corneal topographers YY/T 0787-2024 4.2		2026-07-28
		7	Measurement and report of performance	Opthalmic instruments—Corneal topographers YY/T 0787-2024 4.3		2026-07-28
		8	Colour presentation of results	Opthalmic instruments—Corneal topographers YY/T 0787-2024 4.4		2026-07-28
		9	All items	ophthalmic instruments-slit-lamp microscopes YY/T 0065-2016		2026-07-28
				ophthalmic instruments-Chart projectors ISO 10938：2016		2026-07-28
		10	All items	Ophthalmic instruments -Instrumentsto measure axial distance in the eye YY/T 1484-2016		2026-07-28
		11	All items	Lens ultrasonic removal and vitrectomy devices for ophthalmic surgery YY/T 0766-2009		2026-07-28
		12	All items	Medical electrical equipment-Part 2-58：Particular requirements		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				for the basic safety and essential performance of lens removal devices and virectomy devices for ophthalmic surgery YY 9706.258-2022		
9	Projected and electronic chart displays for visual acuity measurement	1	all items	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025		2026-07-28
		2	Target Shape	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.1.1		2026-07-28
		3	Target Size	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.1.2		2026-07-28
		4	Visual Acuity Registration and Number of Demonstrated Targets	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.1.3		2026-07-28
		5	Test Area and Target Spacing	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.1.4		2026-07-28
		6	Background Brightness	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.1.5		2026-07-28
		7	Target Contrast	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.1.6		2026-07-28
		8	Display Quality	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.1.7		2026-07-28
		9	Resolution	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.1.8		2026-07-28
		10	Projection Range	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.2.1		2026-07-28
		11	Projection Visual Acuity Chart Screen	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.2.2		2026-07-28
		12	Compliance Range	Ophthalmic instrument——Projected and electronic chart displays for visual acuity measurement YY/T 0764-2025 4.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
10	Endoilluminators	1	all items	Ophthalmic instruments——Endoilluminators YY 0792-2024		2026-07-28
		2	Intraocular illuminator light source	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.1.1		2026-07-28
		3	Central Illuminance	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.1.2		2026-07-28
		4	Color Rendering Index	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.1.3		2026-07-28
		5	Correlated Color Temperature	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.1.4		2026-07-28
		6	Meet the light source requirements of the camera system (if applicable)	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.1.5		2026-07-28
		7	Bulb failure protection function	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.1.6		2026-07-28
		8	Temperature of the light guide portion inserted into the eye	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.2.1		2026-07-28
		9	torsion	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.2.2.1		2026-07-28
		10	Stretch	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.2.2.2		2026-07-28
		11	Minimum bend radius	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.2.2.3		2026-07-28
		12	Drop impact	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.2.2.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		13	Size	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.2.3		2026-07-28
		14	Insulation Requirements	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.2.4		2026-07-28
		15	Retinal Protection Measures	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.3.5		2026-07-28
		16	Light Intensity Stability	Ophthalmic instruments——Endoilluminators YY 0792-2024 4.3.6		2026-07-28
11	Diagnostic X-ray generators	1	All items	Medical electrical equipment-Part 2-43:Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures GB 9706.243-2021		2026-07-28
		2	All items	Medical electrical equipment—Part 2-43:Particular requirements for the safety of X-ray equipment for interventional procedures GB 9706.23-2005		2026-07-28
				Medical electrical equipment Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2000		2026-07-28
		3	All items	Medical electrical equipment-Part 2-45:Particular requirements for the basic safety and essential performance of mammographie X-ray equipment and mammographie stereotactic devices GB 9706.245-2020		2026-07-28
		4	All items	Medical electrical equipment--Part 2-45:Particular requirements for the safety of mammographic X-ray equipment and mammographic sterotactic devices GB 9706.24-2005	For use only when referenced or as stipulated in special contracts	2026-07-28
				Medical electrical equipment--Part 2-45:Particular requirements for the safety of mammographic X-ray equipment and		2026-07-28

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		№	Item/ Parameter			
				mammographic sterotactic devices IEC 60601-2-45:2001		
		5	All items	Medical electrical equipment-Part 2-54:Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy GB 9706.254-2020		2026-07-28
		6	All items	Particular specifications for mammographic X-ray equipment YY/T 0706-2017		2026-07-28
		7	All items	Particular specifications for medical X-ray angiography equipment YY/T 0740-2022		2026-07-28
		8	All items	Particular specifications for mini medical diagnostic X-ray equipment YY/T 0347-2009		2026-07-28
		9	All items	Particular specifications for gastrointestinal diagnostic X-ray equipment YY/T 0742-2021		2026-07-28
		10	All items	Particular specifications for mobile C-arm X-ray equipment YY/T 0744-2018		2026-07-28
		11	All items	Particular specifications for mobile radiography X-ray equipment YY/T 0707-2020		2026-07-28
		12	All items	Particular specifications for X-ray equipment installed on the vehicle YY/T 0746-2021		2026-07-28
		13	All items	Particular specifications for X-ray unit for oral cavity YY/T 0010-2020		2026-07-28
		14	All items	Particular specification for oral cavity X-ray equipment for digital tomography YY/T 0795-2022		2026-07-28
		15	All items	General specifications for medical diagnostic X-ray equipment YY/T 0106-2021		2026-07-28
		16	All items	General specifications for digital medical X-ray radiography system YY/T 0741-2018		2026-07-28
		17	All items	Environmental requirements and test methods for medical X-ray equipment YY/T 0291-2016		2026-07-28

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12	X-ray subsidiary and ancillary equipment	1	All items	Medical electrical equipment Part 2: particular requirements for the safety of associated equipment of X-ray equipment GB 9706.14-1997	For use only when referenced or as stipulated in special contracts	2026-07-28
		2	All items	Particular specifications for medical X-ray radiographic table YY/T 0737-2009		2026-07-28
		3	All items	Particular specifications for angiographic injector YY/T 0891-2013		2026-07-28
		4	All items	Particular specifications for X-ray gastrointestinal diagnostic table YY/T 0743-2009		2026-07-28
		5	All items	Particular specifications for cardiovascular table YY/T 0738-2009		2026-07-28
		6	All items	Particular specifications for wall stand of medical X-ray equipment YY/T 0739-2009		2026-07-28
		7	All items	General specifications for X-ray image intensifier TV system for medical diagnosis YY/T 0608-2013		2026-07-28
		8	All items	General specification for medical diagnostic X-ray adjustable beam limiting devices YY/T 0129-2007		2026-07-28
		9	Size and type of plug and socket	specification for high coltage cable assemblies and sockets of Mammographic X-ray equipment YY/T 1541-2017		2026-07-28
		10	Image noise	Particular specifications for mobile X-ray equipment for computed tomography YY/T 1625-2018		2026-07-28
		11	Compatibility	Basic requirments of communication and comformance for medical diagnostic X-ray image equipment Part1: general requiements YY/T 1708.1-2020		2026-07-28
13	X-ray equipment for	1	All items	Medical electrical equipment-Part 2-44:Particular requirements for the basic safety and essential performance of X-ray equipment		2026-07-28

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	computed tomography			for computed tomography GB 9706.244-2020		
		2	All items	Medical electrical equipment-Part 2:Particular requirements for the safety of X-ray equipment for computed tomography GB 9706.18-2006	For use only when referenced or as stipulated in special contracts	2026-07-28
				Medical electrical equipment-Part 2:Particular requirements for the safety of X-ray equipment for computed tomography IEC 60601-2-44:2009+A1：2012+A2:2016		2026-07-28
		3	All items	specifications of X-ray equipment for 64 slice helical computed tomography YY/T 1417-2016		2026-07-28
14	X-ray equipment for computed tomography	1	All Parameters	General specifications for X-ray equipment for computed tomography YY/T 0310-2025		2026-07-28
		2	Imaging Performance	General specifications for X-ray equipment for computed tomography YY/T 0310-2025 5.2		2026-07-28
		3	Dose	General specifications for X-ray equipment for computed tomography YY/T 0310-2025 5.3		2026-07-28
		4	Mechanical and Radiation Output Performance	General specifications for X-ray equipment for computed tomography YY/T 0310-2025 5.4		2026-07-28
		5	Dual-Energy Imaging	General specifications for X-ray equipment for computed tomography YY/T 0310-2025 5.5		2026-07-28
		6	Iterative Reconstruction	General specifications for X-ray equipment for computed tomography YY/T 0310-2025 5.6		2026-07-28
		7	Software Functions	General specifications for X-ray equipment for computed tomography YY/T 0310-2025 5.7		2026-07-28

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		№	Item/ Parameter			
		8	Combined Use with External Equipment	General specifications for X-ray equipment for computed tomography YY/T 0310-2025 5.8		2026-07-28
		9	Requirements for CT Scanners Providing Images for Radiation Therapy Planning (RTP)	General specifications for X-ray equipment for computed tomography YY/T 0310-2025 5.9		2026-07-28
		10	Safety	General specifications for X-ray equipment for computed tomography YY/T 0310-2025 5.10		2026-07-28
15	X-ray generation and limiting device	1	All items	Medical electrical equipment-Part 2:Particular requirements for t he safety of high-voltage generators of diagnostic X-ray generators GB 9706.3-2000	For use only when referenced or as stipulated in special contracts	2026-07-28
				Medical electrical equipment-Part 2:Particular requirements for t he safety of high-voltage generators of diagnostic X-ray generators IEC 60601-2-7-1998		2026-07-28
		2	All items	Medical electrical equipment Part 2:Particular requirements for the safety ofX-ray source assemblies and X-ray tube assembliesfor medical diagnosis GB 9706.228-2020		2026-07-28
16	Diagnostic X-ray generators	1	All items	Medical electrical equipment-Part 1-3:General requirements for basic safety and essential performance-Collateral Standard:Radiation protection in diagnostic X-ray equipment GB 9706.103-2020		2026-07-28
17	Medical radiological protection	1	All items	Medical electrical equipment Part1:General requirements for safety3. Collaterals tandard:requirements for radiation protectionin diagnostic X-ray equipment GB 9706.12-1997	For use only when referenced	2026-07-28

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	equipmen				or as stipulated in special contracts	
				Medical electrical equipment –Part 1-3: General requirements for basic safety and essential performance –Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:1994		2026-07-28
18	phototherapy equipment	1	All items	Medical electrical equipment-Part 2-50:Particular requirements for the basic safety and essential performance of infant phototherapy equipment GB 9706.250-2021		2026-07-28
				Medical electrical equipment-Part 2:Particular requirements for the safety of infant phototherapy equipment IEC 60601-2-50:2005		2026-07-28
		2	All items	Red light therapy equipment YY/T 1496-2016		2026-07-28
		3	All items	Ultraviolet therapy equipment YY/T 0901-2013		2026-07-28
		4	All items	infrared ray cauterization therapy equipment YY/T 0323-2024		2026-07-28
		5	Output Optical Power	infrared ray cauterization therapy equipment YY/T 0323-2024 4.1		2026-07-28
		6	output control	infrared ray cauterization therapy equipment YY/T 0323-2024 4.2		2026-07-28
		7	Timing device	infrared ray cauterization therapy equipment YY/T 0323-2024 4.3		2026-07-28
		8	mark	infrared ray cauterization therapy equipment YY/T 0323-2024 4.4		2026-07-28
		9	accompanying document	infrared ray cauterization therapy equipment YY/T 0323-2024 4.5		2026-07-28

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		10	Electrical safety	infrared ray cauterization therapy equipment YY/T 0323-2024 4.6		2026-07-28
		11	environmental test	infrared ray cauterization therapy equipment YY/T 0323-2024 4.7		2026-07-28
		12	electromagnetic compatibility	infrared ray cauterization therapy equipment YY/T 0323-2024 4.8		2026-07-28
		13	Requirements for LS equipment	infrared ray cauterization therapy equipment YY/T 0323-2024 4.9		2026-07-28
		14	All items	Medical electrical equipment--Part 2-83:Particular requirements for the basicsafety and essential performance of home light therapy equipment GB 9706.283-2022		2026-07-28
		15	All items	Medical electrical equipment--Part 2-75:Particular requirements for the basicsafety and essential performance of photodynamic therapy and photodynamicdiagnosis equipment GB 9706.275-2022		2026-07-28
19	Laser products	1	All items	Medical electrical equipment--Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.222-2022		2026-07-28
		2	All items	Medical electrical equipment--Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment GB 9706.20-2000	For use only when referenced or as stipulated in special contracts	2026-07-28
				Medical electrical equipment--Part 2:Particular requirements for the safety of diagnostic and therapeutic laser equipment IEC 60601-2-22：1995		2026-07-28
		3	All items	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024		2026-07-28

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		4	Principle of classification	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 4		2026-07-28
		5	Determination of attainable emission levels and product classification	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 5		2026-07-28
		6	Engineering protection requirements	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 6		2026-07-28
		7	Markers	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 7		2026-07-28
		8	Other information requirements	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 8		2026-07-28
		9	Other parts of dedicated laser products	Safety of laser products Part1: Equipment classification and requirements GB/T 7247.1-2024 9		2026-07-28
		10	All items	Test methods for laser beam widths,divergence angle and transverse mode GB/T 13739-2011		2026-07-28
		11	All items	Test methods for laser radiation power and its instability GB/T 13863-2011		2026-07-28
		12	All items	Evaluation and test for beam quality of high energy laser GB/T 32831-2016		2026-07-28
		13	All items	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2026-07-28
		14	Therapeutic laser	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2026-07-28
		15	Aiming system	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2026-07-28
		16	Transfer system	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2026-07-28

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		17	Timing apparatus	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2026-07-28
		18	Laser goggle	Laser therapeutic equipment—He-Ne laser equipment GB/T 12257-2023		2026-07-28
		19	Therapeutic laser	Laser therapeutic equipment—Carbon dioxide laser equipment GB/T 11748-2023		2026-07-28
		20	Aiming system	Laser therapeutic equipment—Carbon dioxide laser equipment GB/T 11748-2023		2026-07-28
		21	Transfer system	Laser therapeutic equipment—Carbon dioxide laser equipment GB/T 11748-2023		2026-07-28
		22	Cooling system	Laser therapeutic equipment—Carbon dioxide laser equipment GB/T 11748-2023		2026-07-28
		23	Laser goggle	Laser therapeutic equipment—Carbon dioxide laser equipment GB/T 11748-2023		2026-07-28
		24	All items	Laser confocal scanner YY/T 1154-2009		2026-07-28
		25	All items	Therapeutic Laser Equipment—Pulsed Nd:YAG LaserEquipment for Therapy YY 1300-2016		2026-07-28
		26	All items	Therapeutic Laser Equipment—RubyLaserEquipment for Therapy YY 0983-2016		2026-07-28
		27	All items	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022		2026-07-28
		28	Peak Wavelength	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.1		2026-07-28
		29	Beam Quality	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.2		2026-07-28
		30	Beam Convergence Angle or Divergence Angle	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		31	Spot Diameter at Treatment Position	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.4		2026-07-28
		32	Pulse Characteristics	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.5		2026-07-28
		33	Terminal Output Power (or Energy) Range	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY 1289-2022 5.1.6		2026-07-28
		34	Terminal Output Power (or Energy) Instability	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.1.7		2026-07-28
		35	Reproducibility of Terminal Output Power (or Energy)	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.1.8		2026-07-28
		36	Multi-point Scanning Output Mode	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.1.9		2026-07-28
		37	Targeting Light Wavelength	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.2.1		2026-07-28
		38	Targeting Light Power	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.2.2		2026-07-28
		39	Transmission and/or Observation System Performance	Laser treating equipment-Ophthalmic laser photocoagulators YY 1289-2022 5.3		2026-07-28
		40	All items	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022		2026-07-28
		41	Therapeutic beam	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.1		2026-07-28
		42	Aiming beam	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		43	Fiber transfer system	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.3		2026-07-28
		44	Cooling system	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.4		2026-07-28
		45	Shield goggle	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.5		2026-07-28
		46	Foot pedal switch	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.6		2026-07-28
		47	Safety	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.7		2026-07-28
		48	Environmental test	Laser therapeutic equipment —— Nd: YAG Laser Equipment YY 0307-2022 5.8		2026-07-28
		49	All items	Therapeutic laser equipment—Ho:YAG laser equipment YY 0846-2011/XGI-2021		2026-07-28
		50	All items	Laser therapeutic equipment-Pulsed carbon dioxide laser treating instrument YY/T 0844-2011		2026-07-28
		51	All items	Laser therapeutic equipment—Diode laser equipment for photodynamic therapy YY 0845-2011		2026-07-28
		52	All items	Laser therapeutic equipment Q-Switched Nd:YAG laser equipment YY 1475-2016		2026-07-28
		53	All items	Treating laser equipment Excimer laser cornea ametropia cure system YY 0599-2015		2026-07-28
		54	All items	Q-Switched Nd:YAG Laser Ophthalmic System YY 0789-2010/XGI-2021		2026-07-28
		55	All items	General requirements for therapeutic laser fiber YY/T 0758-2021		2026-07-28
		56	All items	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024		2026-07-28
		57	The use of symbols	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024 4.1		2026-07-28

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		№	Item/ Parameter			
		58	Marking	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024 4.2		2026-07-28
		59	Packaging Label	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024 4.3		2026-07-28
		60	Shelf Packaging or Multi-unit Packaging Label	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024 4.4		2026-07-28
		61	Manufacturer-provided Information	Laser treating equipment—Ophthalmic semiconductor laser photocoagulators YY/T 0486-2024 5		2026-07-28
		62	All items	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020		2026-07-28
		63	Laser output performance of therapeutic equipment	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.2		2026-07-28
		64	Light guide parts	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.3		2026-07-28
		65	Over voltage indication performance	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.4		2026-07-28
		66	appearance	Therapeutic laser equipment-Laser diode irradiation therapeutic equipment for nasal cavity YY/T 1751-2020 4.6		2026-07-28
		67	All items	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016		2026-07-28
		68	laser wavelength	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.1		2026-07-28
		69	laser mode	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.2		2026-07-28

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		№	Item/ Parameter			
		70	laser pulse duration	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.3		2026-07-28
		71	laser pulse train duration	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.4		2026-07-28
		72	maximum laser pulse power	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.5		2026-07-28
		73	maximum average power	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.6		2026-07-28
		74	maximum single pulse energy and duration	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.7		2026-07-28
		75	laser pulse energy	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.8		2026-07-28
		76	laser treatment area size	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.9		2026-07-28
		77	laser treatment speckle energypower density	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.10		2026-07-28
		78	laser divergence angle	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.11		2026-07-28
		79	laser energy instability	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.12		2026-07-28
		80	laser energy repeatibility	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.2.13		2026-07-28
		81	aiming beam wavelength	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.3.1		2026-07-28
		82	aiming beam power	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.3.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		83	laser goggle	Therapeutic laser equpiment-Er:YAG laser equipment for therapy YY 1301-2016 5.6		2026-07-28
20	Excimer laser cornea ametropia equipment	1	All Parameters	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024		2026-07-28
		2	Therapeutic Laser	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.1		2026-07-28
		3	Alignment System	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.2		2026-07-28
		4	Range of Corrected Visual Acuity Area	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.3		2026-07-28
		5	Refractive Correction Range	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.4		2026-07-28
		6	Laser Gas Supply Circuit	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.5		2026-07-28
		7	Eye Tracking System	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.6		2026-07-28
		8	Aiming System	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.7		2026-07-28
		9	Surgical Microscope	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.8		2026-07-28
		10	Patient Support System	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.9		2026-07-28
		11	Auxiliary Light Source	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.10		2026-07-28
		12	Foot Switch	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.11		2026-07-28
		13	Photobiological Hazard	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.12		2026-07-28
		14	Safety	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.13		2026-07-28

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		№	Item/ Parameter			
		15	Electromagnetic Compatibility (EMC)	Lasertherapeuticequipment—Excimer laser cornea ametropia equipment YY 0599-2024 4.14		2026-07-28
21	Operation microscopes	1	All Parameters	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025		2026-07-28
		2	General Requirements	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.1		2026-07-28
		3	Optical and Mechanical Requirements	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.2		2026-07-28
		4	Imaging Parfocality	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.3		2026-07-28
		5	Relative Tolerance of Field of View	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.4		2026-07-28
		6	Field of View Center Offset	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.5		2026-07-28
		7	Visual Accessories	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.6		2026-07-28
		8	Illumination Device	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.7		2026-07-28
		9	Optical Cleanliness	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.8		2026-07-28
		10	Noise	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.9		2026-07-28
		11	Frame Performance	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.10		2026-07-28
		12	Electrical Safety	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.11		2026-07-28
		13	Electromagnetic Compatibility	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods GB/T 11239.1-2025 4.12		2026-07-28

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		№	Item/ Parameter			
			(EMC)			
22	Optical imaging diagnostic equipment	1	All items	Operation microscopes-Part 1:Requirements and test methods GB 11239.1-2005		2026-07-28
		2	All items	Stereomicroscopes-Part 1 :Stereomicroscopes for general use GB/T 19864.1-2013		2026-07-28
				Stereomicroscopes-Part 2:High performance stereomicroscope GB/T 19864.2-2013		2026-07-28
				Testing of stereomicroscope GB/T 19863-2005		2026-07-28
		3	All items	Biological microscope GB/T 2985-2008		2026-07-28
		4	All items	Micro-circulation microscopes YY/T 0067-2007		2026-07-28
		5	All items	Microscope-Objectives GB/T 2609-2015		2026-07-28
		6	All items	Microscope-Oculars(eyepieces) GB/T 9246-2008		2026-07-28
		7	All items	Microscopes-Condensers GB/T 9247-2008		2026-07-28
		8	All items	Microscopes-Marking of objectives and eyepieces GB/T 22056-2018		2026-07-28
		9	All items	Microscopes-Imaging distances related to mechanical reference planes—Part 1:Tube length 160mm GB/T 22055-2022		2026-07-28
		10	All items	Microscopes-Dimensions and positions of holes for stage clips and attachable mechanical stage on microscope stage JB/T 8230.7-1999		2026-07-28
		11	All items	Microscopes-connecting dimensions of dismountable condenser and colour filter JB/T 8230.8-1999		2026-07-28
		12	All items	Medical luminaires—Medical head-mounted luminaires YY/T 0932-2014		2026-07-28

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		№	Item/ Parameter			
		13	All items	Infrared examining equipment for mammary gland YY/T 0324-2019		2026-07-28
		14	All items	Medical electrical equipment –Part 2-57: Particular requirements for the basic safety and essential performanceof non-laser light source equipment intended for therapeutic, diagnostic,monitoring and cosmetic/aesthetic use IEC60601-2-57：2011		2026-07-28
23	Lung ventilator	1	All items	Medical eletrical equipment-Part 2-90:Particular requirements for the basic safety and essential performance of respiratory high flow therapy equipment GB 9706.290-2022		2026-07-28
		2	All items	Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors GB 9706.255-2022		2026-07-28
		3	All items	Medical electrical equipment — Part 2-79:Particular requirements for basic safetyand essential performance of ventilatory support equipment for ventilatoryimpairment YY 9706.279-2023		2026-07-28
		4	All items	Medical electrical equipment — Part 2-80:Particular requirements for basicsafety and essential performance of ventilatory support equipment forventilatory insufficiency YY 9706.280-2023		2026-07-28
		5	All items	Medical eletrical equipment-Part 2-84:Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services equipment YY 9706.284-2023		2026-07-28
		6	All items	Medical eletrical equipment-Part 2-72:Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients YY 9706.272-2021		2026-07-28
24	critical care ventilators	1	All items	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023		2026-07-28
		2	Additional requirements for ESSENTIAL PERFORMANCE	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.4.3.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.4.3.101		2026-07-28
		3	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.4.6		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.4.6		2026-07-28
		4	Overpressure requirement	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.4.11.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.4.11.101		2026-07-28
		5	Additional requirements for general requirements for testing ofME EQUIPMENT	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.5.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.5.101		2026-07-28
		6	Consult ACCOMPANYING DOCUMENTS	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.3		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.7.2.3		2026-07-28
		7	Additional requirements for marking on the outside of ME EQUIPMENT orME	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.7.2.101		2026-07-28

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		№	Item/ Parameter			
			EQUIPMENT parts			
		8	Additional requirements for ACCESSORIES	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.4.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2011 201.7.2.4.101		2026-07-28
		9	Additional requirements for physiological effects	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.13.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.7.2.13.101		2026-07-28
		10	Additional requirements for protective packaging	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.2.17.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.7.2.17.101		2026-07-28
		11	Unit of measure	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.4.3		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.7.4.3		2026-07-28
		12	Additional general requirements	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.7.9.1		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.7.9.1		2026-07-28
		13	Additional requirements for warnings and safety notices	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.9.6.2.1.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.9.6.2.1.101		2026-07-28

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		№	Item/ Parameter			
		14	Additional requirements for suction procedures	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.9.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.9.101		2026-07-28
		15	Leakage	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.11.6.4		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.11.6.4		2026-07-28
		16	Additional requirements for ingress of water or particulate matter intoME EQUIPMENT or ME SYSTEM	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.11.6.5.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.11.6.5.101		2026-07-28
		17	Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.11.6.6		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.11.6.6		2026-07-28
		18	Additional requirements for interruption of the powersupplySUPPLY MAINS to ME EQUIPMENT	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.11.8.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.11.8.101		2026-07-28
		19	Volume-controlled breath type	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.1.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.12.1.101		2026-07-28

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		№	Item/ Parameter			
		20	Pressure-controlled breath type	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.1.102		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.12.1.102		2026-07-28
		21	DELIVERED VOLUME MONITORING	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.1.103		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.12.1.103		2026-07-28
		22	Response of the VENTILATOR to an increase in O2 concentration	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.1.104		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.12.1.104		2026-07-28
		23	Protection against hazardous output	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.4		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.12.4		2026-07-28
		24	Protection against accidental adjustments	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.12.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.12.101		2026-07-28
		25	HAZARDOUS SITUATIONS and fault conditions	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.13		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.13		2026-07-28
		26	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.14		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.14		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		27	Construction of ME EQUIPMENT	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.15		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.15		2026-07-28
		28	ME SYSTEMS	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.16		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.16		2026-07-28
		29	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.17		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.17		2026-07-28
		30	Gas connections	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.101		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.101		2026-07-28
		31	Requirements for the VBS and ACCESSORIES	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.102		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.102		2026-07-28
		32	Spontaneous breathing during loss of power supply	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.103		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.103		2026-07-28
		33	Training	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.104		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.104		2026-07-28

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		34	Indication of duration of operation	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.105		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.105		2026-07-28
		35	SIGNAL INPUTOUTPUT PART	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.106		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.106		2026-07-28
		36	Display loops	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.107		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.107		2026-07-28
		37	Timed ventilatory pause	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 201.108		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 201.108		2026-07-28
		38	Medical electrical equipment – Part 1-6: General requirements for basic safetyand essential performance – Collateral Standard: Usability	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 206		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 206		2026-07-28
		39	Medical electrical equipment – Part 1-8: General requirements for basic safetyand	Particular requirements for basic safety and essential performance of critical care ventilators GB 9706.212-2020 208		2026-07-28
				Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12：2023 208		2026-07-28

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			essential performance – Collateral Standard: General requirements, tests andguidance for alarm systems in medical electrical equipment and medical electricalsystems			
		40	All items	Medical electrical equipment-Part 2:Particular requirements for the safety of lung ventilator GB 9706.28-2006	For use only when referenced or as stipulated in special contracts	2026-07-28
		41	All items	Medical suture needle YY 0042-2018		2026-07-28
		42	All items	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 0461-2003		2026-07-28
25	high-frequency ventilators	1	All items	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025		2026-07-28
		2	General requirements	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.4		2026-07-28
		3	General requirements for testing of medical	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.5		2026-07-28

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			electrical equipment			
		4	Classification of ME equipment and ME systems	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.6		2026-07-28
		5	ME equipment identification, marking and documentation	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.7		2026-07-28
		6	Protection of medical electrical equipment against electric shock hazards	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.8		2026-07-28
		7	Proticition Against Mechannical Hazards of ME Equipment and ME Systems	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.9		2026-07-28
		8	Proticition Against Unwanted and Excessive Radiation Hazards	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.10		2026-07-28
		9	Proticition Against Excessive Temperatures and Other Hazards	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.11		2026-07-28
		10	Accuracy of Controls and Instruments and Protection Against	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.12		2026-07-28

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			Hazardous Outputs			
		11	Hazardous Situations and Fault Conditions	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.13		2026-07-28
		12	Programmable Electrical Medical Systems（PEMS）	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.14		2026-07-28
		13	Construction of ME Equipment	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.15		2026-07-28
		14	ME Systems	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.16		2026-07-28
		15	Electromagnetic Compatibility of ME Equipment and ME Systems	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.17		2026-07-28
		16	Gas connections	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.101		2026-07-28
		17	Requirements for high frequency ventilation respiratory systems and accessories	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.102		2026-07-28
		18	Spontaneous breathing during loss of power supply	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.103		2026-07-28

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		19	Indication of duration of operation	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.104		2026-07-28
		20	Functional connection	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.105		2026-07-28
		21	Display loops	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.106		2026-07-28
		22	Temporary suspension of high frequency oscillation for a limited time	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 201.107		2026-07-28
		23	Electromagnetic interference - Requirements and tests	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 202		2026-07-28
		24	usability	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 206		2026-07-28
		25	General requirements, testing, and guidelines for alarm systems in medical electrical equipment and medical electrical systems	Medical eletrical equipment-Part 2-87:Particular requirements for the basic safety and essential performance of high-frequency ventilators YY 9706.287—2025 208		2026-07-28
26	anaesthetic	1	All items	Medical eletrical equipment-Part 2-13:Particular requirements for		2026-07-28

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	system			the basic safety and essential performance of an anaesthetic workstation GB 9706.213-2021		
		2	All items	Medical electrical equipment-Part2:Particular requirements for the safety and essential performance of anaesthetic systems GB 9706.29-2006	For use only when referenced or as stipulated in special contracts	2026-07-28
		3	All items	Inhalational anaesthesia system-Part 1:Anaesthetic breathing system for adults YY 0635.1-2013		2026-07-28
		4	All items	Inhalational anaesthesia system-Part 2:Anaesthetic gas scavenging systems transfer and receiving systems YY 0635.2-2009		2026-07-28
		5	All items	Inhalational anaesthesia system-Part 3:Anaesthetic vapour delivery devices YY 0635.3-2009		2026-07-28
		6	All items	Inhalational anaesthesia system-Part 4:Requirements for anaesthetic ventilators YY 0635.4-2009		2026-07-28
27	ventilators、anaesthetic、Emergency equipment 、auxiliary device	1	All items	Medical eletrical equipment-Part 2-70:Particular requirements for the basic safety and essential performance of sleep apnaea breathing therapy equipment YY 9706.270-2021		2026-07-28
		2	All items	Sleep apnoea breathing therapy-Part 1：Sleep apnoea breathing therapy devices YY 0671.1-2009	For use only when referenced or as stipulated in special contracts	2026-07-28
		3	All items	Sleep apnoea breathing therapy-Part 1：Sleep apnoea breathing therapy devices YY/T 0671-2021		2026-07-28

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		4	All items	Medical suction equipment-Part1：Electrically powered suction equipment-Safety requirements YY 0636.1-2021		2026-07-28
		5	All items	Medical suction equipment-Part2：Manually powered suction equipment YY 0636.2-2021		2026-07-28
		6	All items	Medical suction equipment—Part3:Suction equipment powered a vacuum or pressure source YY 0636.3-2021		2026-07-28
		7	All items	Medical eletrical equipment-Part 2-74:Particular requirements for basic safety and essential performance of respiratory humidifying equipment YY 9706.274-2022		2026-07-28
		8	All items	Anaesthetic reservoir bags YY/T 0978-2016		2026-07-28
		9	All items	Medical electrical equipment-Part 2-4：Particular requirements for the basic safety and essential performance of cardiac defibrillators GB 9706.204-2022		2026-07-28
		10	All items	Semi-Automatic External Defibrillato GB9706.8-2009	For use only when referenced or as stipulated in special contracts	2026-07-28
				Semi-Automatic External Defibrillato IEC 60601-2-4:2002		2026-07-28
				Semi-Automatic External Defibrillato IEC 60601-2-4:2003		2026-07-28
		11	Partial items	Oxygen concentrators for medical use-Safety requirements YY 9706.269-2021	except 50.4,50.5	2026-07-28
		12	All items	Respiratory tract humidifiers for medical use-Particular requirements for respiratory humidification systems YY 0786-2010	For use only when referenced	2026-07-28

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					or as stipulated in special contracts	
		13	All items	Buoy type oxygen inhalator YY 1107-2003		2026-07-28
28	Suction catheters for use in the respiratory tract	1	All items	Suction catheters for use in the respiratory tract YY/T 0339—2024		2026-07-28
		2	material	Suction catheters for use in the respiratory tract YY/T 0339—2024 5		2026-07-28
		3	Design requirements	Suction catheters for use in the respiratory tract YY/T 0339—2024 6		2026-07-28
		4	the requirements for Suction catheters for use in the respiratory tract by sterile	Suction catheters for use in the respiratory tract YY/T 0339—2024 7		2026-07-28
		5	Package	Suction catheters for use in the respiratory tract YY/T 0339—2024 8		2026-07-28
		6	product information	Suction catheters for use in the respiratory tract YY/T 0339—2024 9		2026-07-28
29	Gas mixers	1	All items	Gas mixers for medical use-Standalone gas mixers YY/T0893-2023		2026-07-28
		2	basic performance requirements	Gas mixers for medical use-Standalone gas mixers YY/T0893-2023 4		2026-07-28
		3	general requirement	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 5		2026-07-28
		4	materials	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 6		2026-07-28

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		5	normal operative condition	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 7		2026-07-28
		6	air intake pressure requirements	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 8		2026-07-28
		7	back-draft	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 9		2026-07-28
		8	leak	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 10		2026-07-28
		9	alarm system	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 11		2026-07-28
		10	oxygen concentration indicator accuracy	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T0893-2023 12		2026-07-28
		11	air failure	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 13		2026-07-28
		12	gas connection	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 14		2026-07-28
		13	air intake filter	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 15		2026-07-28
		14	flow controller	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 16		2026-07-28
		15	Low pressure hose assembly	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 17		2026-07-28
		16	electric safety	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans		2026-07-28

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				YY/T0893-2023 18		
		17	label	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 19		2026-07-28
		18	attached documents	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T0893-2023 20		2026-07-28
30	Anaesthetic equipment	1	All items	Breathing tubes intended for use with aneasthetic apparatus and ventilators YY/T 1040.1-2015		2026-07-28
		2	All items	Anaesthetic and respiratory equipment—Conical connectors—Part 2:Screw-threaded weight-bearing connectors YY/T 1040.2-2008		2026-07-28
		3	All items	Anaesthetic and respiratory equipment-Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans YY/T 1438-2016		2026-07-28
		4	All items	Anaesthetic and respiratory equipment —— User-applied labels for syringes containing drugs used during anaesthesia —— Colours, design and performance YY/T 0975-2016		2026-07-28
		5	All items	Anaesthetic vaporizers—Agent-specific filling systems YY/T 0755-2009		2026-07-28
		6	All items	Breathing system filters for anaesthetic and respiratory use—Part2:Non-filtration aspects YY/T 0753.2-2009		2026-07-28
		7	All items	Anaesthetic and respiratory equipment-Supralaryngeal airways and connectors YY/T 0985-2016		2026-07-28
31	Medical oxygen production equipment	1	All items	Oxygen concentrator supply systems for use with medical gas pipeline systems YY/T 1468-2016		2026-07-28
		2	All items	Oxygen supplies for medicine and aircraft breathing GB/T 8982-2025		2026-07-28

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32	Surgical Instruments	1	All items	Surgical Instruments—Gill shaft,Bolt and Rivet YY/T 0173-2010		2026-07-28
		2	All items	Rectosigmoid biopsy forceps YY/T 0178-2010		2026-07-28
		3	All items	Naso-pharyngeal biopsy forceps YY/T 0246-2010		2026-07-28
		4	All items	Ophthalmic scissors YY/T 0176.9-2011		2026-07-28
		5	All items	General specification for ophthalmic knives YY/T 0072-2010		2026-07-28
		6	All items	Ophthalmic Forceps YY/T 0819-2010		2026-07-28
		7	All items	Electric surgical equipment for osseous tissue YY/T 0752-2016		2026-07-28
		8	All items	Battery power supply surgical equipment for osseous tissue YY/T 0904-2013		2026-07-28
		9	All items	Abdominal suction tube YY/T 0191-2011		2026-07-28
		10	All items	Plasma surgical equipment YY/T 1409-2016		2026-07-28
		11	All items	Cardiopulmonary bypass systems—Centrifugal pump YY 1412-2016		2026-07-28
		12	All items	Metal plating classification technology condition of parts YY/T 0076-1992		2026-07-28
		13	All items	Cutting tools for electric osseous tissue surgical equipment--Part 4：Milling cutter YY/T 1629.4-2020		2026-07-28
		14	All items	Cutting tools for electric osseous tissue surgical equipment--Part 5：Saw blade YY/T 1629.5-2020		2026-07-28
		15	All items	Cutting tools for electric osseous tissue surgical equipment--Part 6：Rasp YY/T 1629.6-2021		2026-07-28

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		16	All items	Disposable abdominal trocars YY/T 1710-2020		2026-07-28
33	Cranial perforator	1	All items	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
		2	Structure and size	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
		3	Appearance	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
		4	Requirement	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
		5	Surface roughness	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
		6	Hardness	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
		7	Interface strength	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
		8	Adaptability	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
		9	Corrosion resistance	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
		10	Cleaning, disinfection or sterilization	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
		11	Sterile products should be sterile	Cutting tools for eletric osseous tissue surgical equipment-Part 2:Cranial perforator YY/T 1629.2-2018		2026-07-28
34	Burs	1	All items	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		2	Structure and size	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		3	Edge size	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		4	Surface roughness	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		5	Rod straightness	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		6	Radial circular runout of edge	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		7	Hardness	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		8	Connecting Strength	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		9	Edge strength	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		10	Permanent deformation	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		11	Corrosion resistance	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		12	Tolerance to disinfection or sterilization	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		13	Aseptic requirements	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		14	Ethylene oxide residue	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
		15	Adaptability	Cutting tools for eletric osseous tissue surgical equipment-Part 1:Burs YY/T 1629.1-2018		2026-07-28
35	Ultrasonic surgical equipment for	1	All items	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	osseous tissue	2	Appearance and structure	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		3	Display and Control	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		4	Tip main amplitude	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		5	Tip transverse amplitude	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		6	Excitation frequency	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		7	Tip vibration frequency	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		8	Derived Output Sound Power	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		9	Duty cycle	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		10	Static (no-load) power	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		11	Maximum electric power	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		12	Power reserve index	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		13	Main Sound Output Area	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		14	Acoustic output area of secondary transverse vibration	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		15	Liquid flow rate	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Noise	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
		17	Characteristics to be published in the specification	Ultrasonic surgical equipment for osseous tissue YY/T 1601-2018		2026-07-28
36	Electrical acoustic measurement and analysis equipment	1	All items	Audiometers Part2:Equipment for speech audiometry GB/T 7341.2-1999		2026-07-28
		2	All items	Audiometers Part4:Equipment for extended high-frequency audiometry GB/T 7341.4-1999		2026-07-28
		3	All items	Electroacoustics-Audiological equipment-Part 1:Pure-tone audiometers GB/T 7341.1-2010		2026-07-28
		4	All items	Instruments for the measurement of aural acoustic impedance/admittance GB/T 7341.5-2018		2026-07-28
37	Hearing Aids	1	All items	Electroacustics-General specification for hearing aids GB/T 14199-2010		2026-07-28
		2	All items	Electroacoustics-Hearing aids-Part1:Hearing aids with induction pick-up coil input GB/T 25102.1-2010		2026-07-28
		3	All items	Electroacoustics-hearing aids-Part 2:Hearing aids with automatic gain control circuits GB/T 25102.2-2010		2026-07-28
		4	All items	Electroacoustics-Hearing aids-Part 0:Measurement of electroacoustical characteristics GB/T 25102.100-2010		2026-07-28
		5	All items	Electroacoustics - Hearing aids - Part13:Electromagnetic compatibility(EMC) GB/T 25102.13 -2010		2026-07-28
38	Medical endoscope	1	All items	Medical electrical equipment-Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment GB 9706.218-2021		2026-07-28
		2	All items	Medical electrical equipment- Part2 :Particular requirements for the safety of endoscopic equipment GB 9706.19-2000	For use only when referenced or as	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					stipulated in special contracts	
				Medical electrical equipment- Part3 :Particular requirements for the safety of endoscopic equipment IEC 60601-2-18：2009		2026-07-28
		3	All items	Medical endoscopes Fiber optical cable for lighting YY/T 0763-2009/XGI-2023		2026-07-28
		4	All items	Endoscopic washing station YY/T 0992-2023		2026-07-28
		5	Partial items	Medical Endoscopes—Capsule Endoscopes YY/T 1298-2016/XGI-2019	except4.5.1、4.5.2	2026-07-28
		6	All items	Medical Endoscopes-Rigid Endoscope-Part 1:Optical properties and test methods YY 0068.1-2008		2026-07-28
		7	All items	Medical endoscopes-Rigid endoscope-Part 2:Mechanical properties and test methods YY/T 0068.2-2008		2026-07-28
		8	All items	Medical endoscopes-Rigid endoscope-Part 3:Marking and instruction manual YY/T 0068.3-2008		2026-07-28
		9	All items	Medical Endoscopes —Rigid endoscope —part 4:Fundamental requirement YY 0068.4-2009 YY 0068.4-2023		2026-07-28
		10	All items	Medical endoscopes—Rigid resectosocope YY/T 0619—2017		2026-07-28
		11	All items	General specification of medical rigid trachea endoscope YY/T 0069-2009		2026-07-28
		12	All items	Esophagoscope YY/T 0070-2018		2026-07-28
		13	All items	Sigmoidos-copy and rectoscope set YY/T 0071-2018		2026-07-28
		14	All items	Large intestine fiber endoscope YY/T 0283-2007		2026-07-28
		15	All items	Anoscope YY/T 0190-2008		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	All items	Upper gastro intestinal fiberscope YY/T 1028-2023		2026-07-28
		17	All items	Nasal specula YY/T 0189-2008		2026-07-28
39	Laryngoscopes for tracheal intubation	1	All Parameters	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation YY 0499-2023		2026-07-28
		2	General Requirements	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation YY 0499-2023 4		2026-07-28
		3	Materials	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation YY 0499-2023 5		2026-07-28
		4	Design Requirements	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation YY 0499-2023 6		2026-07-28
		5	Performance Requirements	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation YY 0499-2023 7		2026-07-28
		6	Information Provided by the Manufacturer	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation YY 0499-2023 9		2026-07-28
40	robotically-assisted laparoscopic surgical system	1	All items	Robotically-assisted laparoscopic surgical system YY/T 1941-2024		2026-07-28
		2	Master tool manipulator workspace	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.1.1		2026-07-28
		3	Master-slave clutch control	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.1.2		2026-07-28
		4	End effector effective workspace	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.2.1		2026-07-28
		5	Remote center of motion accuracy	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.2.2		2026-07-28
		6	Effective operating force of instrument	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.2.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			arm			
		7	Jaw Opening/Closing Force	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.2.4		2026-07-28
		8	Motion control of endoscope	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.1		2026-07-28
		9	Remote center of motion adjustment function	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.2		2026-07-28
		10	Master-slave operation distance accuracy	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.3.1		2026-07-28
		11	Master-slave operation distance repeatability	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.3.2		2026-07-28
		12	Master-slave operation posture accuracy	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.4.1		2026-07-28
		13	Master-slave operation posture repeatability	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.4.2		2026-07-28
		14	Master-slave control delay	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.5		2026-07-28
		15	System display delay	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.6		2026-07-28
		16	Master-slave distance scaling ratio	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.3.7		2026-07-28
		17	Braking distance	Robotically-assisted laparoscopic surgical system YY/T 1941-		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				2024 4.4.1		
		18	Slip distance	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.2		2026-07-28
		19	Speed limitation	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.3		2026-07-28
		20	Collision protection	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.4		2026-07-28
		21	Safety interlock	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.5		2026-07-28
		22	Patient release	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.4.6		2026-07-28
		23	Mechanical interface requirements	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.1		2026-07-28
		24	Communication and identification of robotic surgical instruments with RALS	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.2		2026-07-28
		25	Degrees of freedom of robotic surgical instruments	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.3		2026-07-28
		26	Compatibility between robotic surgical instruments and trocar sleeves	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.4		2026-07-28
		27	Sealing performance of robotic surgical instruments	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		28	Requirements for reusable robotic surgical instruments	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.6		2026-07-28
		29	Sterility	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.7.1		2026-07-28
		30	Ethylene oxide residue	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.7.2		2026-07-28
		31	Appearance	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.8		2026-07-28
		32	Dimensions	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.9		2026-07-28
		33	Hardness	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.10		2026-07-28
		34	Corrosion resistance	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.11		2026-07-28
		35	Surface roughness	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.5.12		2026-07-28
		36	Self-test function	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.6.1		2026-07-28
		37	Prompt information	Robotically-assisted laparoscopic surgical system YY/T 1941-2024 4.6.2		2026-07-28
41	Video endoscopes	1	All items	Medical endoscopes-Video endoscopes YY/T 1587-2018		2026-07-28
		2	Contact materials with patient	Medical endoscopes-Video endoscopes YY/T 1587-2018		2026-07-28
		3	Field angle	Medical endoscopes-Video endoscopes YY/T 1587-2018		2026-07-28
		4	Relative self-effect of illumination light luminosity	Medical endoscopes-Video endoscopes YY/T 1587-2018		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Brightness response characteristics	Medical endoscopes-Video endoscopes YY/T 1587-2018		2026-07-28
		6	SNR	Medical endoscopes-Video endoscopes YY/T 1587-2018		2026-07-28
		7	SFR	Medical endoscopes-Video endoscopes YY/T 1587-2018		2026-07-28
		8	Static image tolerance	Medical endoscopes-Video endoscopes YY/T 1587-2018		2026-07-28
		9	mechanical character	Medical endoscopes-Video endoscopes YY/T 1587-2018		2026-07-28
42	Ultrasound endoscope	1	All items	ultrasound endoscpe YY/T 1676-2020		2026-07-28
		2	acoustic working frequency	ultrasound endoscpe YY/T 1676-2020 4.1		2026-07-28
		3	depth of penetration	ultrasound endoscpe YY/T 1676-2020 4.2		2026-07-28
		4	lateral resolution	ultrasound endoscpe YY/T 1676-2020 4.3		2026-07-28
		5	axial resolution	ultrasound endoscpe YY/T 1676-2020 4.4		2026-07-28
		6	dead zone	ultrasound endoscpe YY/T 1676-2020 4.5		2026-07-28
		7	slice thickness	ultrasound endoscpe YY/T 1676-2020 4.6		2026-07-28
		8	Horizontal geometric position accuracy	ultrasound endoscpe YY/T 1676-2020 4.7		2026-07-28
		9	Longitudinal geometric position accuracy	ultrasound endoscpe YY/T 1676-2020 4.8		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		10	Measurement deviation of perimeter and area	ultrasound endoscpe YY/T 1676-2020 4.9		2026-07-28
		11	M-mode performance index	ultrasound endoscpe YY/T 1676-2020 4.10		2026-07-28
		12	three-dimensional ultrasonography	ultrasound endoscpe YY/T 1676-2020 4.11		2026-07-28
		13	Geometric position accuracy of retraction direction	ultrasound endoscpe YY/T 1676-2020 4.12		2026-07-28
		14	Image geometric distortion	ultrasound endoscpe YY/T 1676-2020 4.13		2026-07-28
		15	ultrasonic colour flow imaging performance	ultrasound endoscpe YY/T 1676-2020 4.14		2026-07-28
		16	angle of ultrasound visual field	ultrasound endoscpe YY/T 1676-2020 4.15		2026-07-28
43	Roller irrigation and suction equipment	1	All items	Medical endoscopes--Endoscope functional supply units--Roller irrigation and suction equipment YY/T 0863-2011		2026-07-28
		2	All items	Madical endoscopes--Endoscope funtional supply units--Irrigation pump YY/T 0864-2011		2026-07-28
		3	All items	Medical Endoscopes-Endoscope supply units-insufflators YY 0843-2011		2026-07-28
		4	All items	Medical Endoscopes—Endoscope supply units—cold light sources YY/T 1081-2011		2026-07-28
		5	All items	Endoscopic surgical instruments-Reusable abdominal suction and irrigation tubes YY/T 1846-2022		2026-07-28
		6	All items	Madical endoscopes--Endoscope surgical equipment--Shaver YY/T 0955-2014		2026-07-28

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44	Medical endoscopes-Endoscope supply units-Video camera system	1	All items	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2026-07-28
		2	MTF	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2026-07-28
		3	focal length	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2026-07-28
		4	Brightness response characteristics	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2026-07-28
		5	SNR	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2026-07-28
		6	SFR	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2026-07-28
		7	Static image tolerance	Medical endoscopes- Endoscope supply units-Video camera system YY/T 1603-2018		2026-07-28
45	Medical Endoscope endoscope accessories	1	All items	Medical Endoscope endoscope accessories cytology brush YY/T 0930-2014		2026-07-28
		2	All items	Medical Endoscopes — Endotherapy Device —Palmate Retractor YY/T 1446—2016		2026-07-28
		3	All items	Medical endoscopes-Endoscope device-Curette YY/T 1297—2015		2026-07-28
		4	All items	Medical endoscopes -Endotherapy device -Needle forceps YY/T 0943-2014		2026-07-28
		5	All items	Medical endoscopes — Endotherapy device —Grasping forceps YY/T 0940-2014		2026-07-28
		6	All items	Medical endoscopes — Endotherapy device —Separating forceps YY/T 0944-2014		2026-07-28
		7	All items	Medical endoscopes — Endotherapy device —Punch forceps YY/T 0941-2014		2026-07-28
		8	All items	Medical Endoscope endoscope device loop ligature YY/T 0931-2014/XGI-2020		2026-07-28

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		9	All items	Medical Endoscopes — endotherapy device — stone retrieval forceps YY/T 0847-2011		2026-07-28
		10	All items	Madical endoscopes--endoscope accessories--bridges YY/T 0922-2014		2026-07-28
		11	All items	Medical endoscopes--Endoscope accessories--Sheaths YY/T 0842-2011		2026-07-28
		12	All items	Hose biopsy sampling forceps used with endoscope-General specifications YY/T 1076-2004		2026-07-28
		13	All items	Endoscopic instruments-Part1:Trocars for laparoscope use YY/T 1783-2021		2026-07-28
		14	All items	Endoscopy instruments--Part 2：Laparoscopy scissors YY/T 0672.2-2011		2026-07-28
		15	All items	Laryngoscopic fittings-Part 1:Conventional hook-on type handle-blade fittings YY 0498.1-2004		2026-07-28
		16	All items	Laryngoscopic fittings-Part 2:Miniature electric lamps-Screw threads and sockets for conventional blades YY 0498.2-2004		2026-07-28
46	Endoscopic surgical instrument-Endoscopic cutter stapler and reload	1	partial items	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021		2026-07-28
		2	appearance	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.2		2026-07-28
		3	corrosion resistance	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.3		2026-07-28
		4	surface roughness	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.4		2026-07-28
		5	size	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.5		2026-07-28
		6	hardness	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.6		2026-07-28
		7	assemblability	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.7		2026-07-28

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		№	Item/ Parameter			
		8	flexibility	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.8		2026-07-28
		9	performance in use	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.9		2026-07-28
		10	Cutting blade sharpness	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.10		2026-07-28
		11	pressure resistance	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.11		2026-07-28
		12	protective device	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.12		2026-07-28
		13	Compatibility with the puncture device	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.13		2026-07-28
		14	manual	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 4.19		2026-07-28
		15	tag and manual	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 7		2026-07-28
		16	package	Endoscopic surgical instrument-Endoscopic cutter stapler and reload YY/T 1797-2021 8		2026-07-28
47	ultrasonic medical diagnostic and monitoring equipment	1	All items	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020		2026-07-28
		2	General requirements	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.4		2026-07-28
		3	ME equipment identification, marking and documentation	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.7		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Protection of ME equipment against electric shock hazard	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.8		2026-07-28
		5	Protection against unnecessary or excessive radiation hazards (sources)	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.10		2026-07-28
		6	Protection against extreme temperature and other hazards (sources)	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.11		2026-07-28
		7	Accuracy of controller and instrument and protection of dangerous output	Medical electrical equipment Part 2-38: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.12		2026-07-28
		8	Dangerous situation and fault status of ME equipment	Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment GB 9706.237-2020 201.13		2026-07-28
		9	All items	Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment GB 9706.9-2009		2026-07-28
				Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2001 + Am1:2004 + Am2:2005		2026-07-28
		10	All items	Ultrasonics-Hand-held probe Doppler foetal heartbeat detectors-Performance requirements and methods of measurement and reporting YY/T 0749-2009		2026-07-28

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		№	Item/ Parameter			
		11	All items	Ultrasonic Doppler fetal monitor YY/T 0449-2018		2026-07-28
		12	All items	Ultrasonic Doppler foetal heartbeat detector YY/T 0448-2019		2026-07-28
		13	All items	Ultrasound Bone Sonometers YY/T 0774-2019		2026-07-28
		14	All items	Ultrasound transcranial Doppler system YY/T 0593-2022		2026-07-28
		15	All items	Methods of measuring the frequency of medical diagnostic and monitoring ultrasonic equipment YY/T 1142-2013		2026-07-28
		16	All items	Requirement for the declaration of the acoustic output of medical diagnostic ultrasonic equipment GB/T 16846-2008		2026-07-28
		17	All items	Testing methods for M-mode of ultrasonic diagnostic equipment YY/T 0108-2008		2026-07-28
		18	All items	Measurement methods of output power for medical diagnostic ultrasonic equipments YY/T 1084-2015		2026-07-28
		19	All items	Ultrasonics - Field characterization -Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields YY/T 0642-2022		2026-07-28
		20	Part of Items	Measuring methods for beam area of medical ultrasound equipment transducer YY/T 1278-2015	Except for 4.3	2026-07-28
		21	All items	Ultrasound - Test methods of performance for quasi-static strain sonoelasticity YY/T 1419-2016		2026-07-28
		22	All items	Environmental requirement and test methods for medical ultrasonic equipment YY/T 1420-2016		2026-07-28
		23	All items	B mode ultrasonic diagnostic equipment GB 10152-2009		2026-07-28
		24	All items	Medical ultrasound equipment class series-Part 1: B mode ultrasound diagnostic equipment YY/T 0162.1-2009		2026-07-28
48	intravascularultrasound (	1	All items	Generaltechnicalrequirementsfor intravascularultrasound (IVUS) diagnosticequipment YY/T 1659-2019		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	IVUS)diagnosticequipment	2	acoustic working frequency	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.1		2026-07-28
		3	radius of imaging	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.2		2026-07-28
		4	axial resolution	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.3		2026-07-28
		5	lateral resolution	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.4		2026-07-28
		6	pullback resolution	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.5		2026-07-28
		7	Longitudinal geometric position accuracy	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.6		2026-07-28
		8	Horizontal geometric position accuracy	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.7		2026-07-28
		9	Geometric position accuracy of retraction direction	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.8		2026-07-28
		10	Image geometric distortion	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.9		2026-07-28
		11	Appearance and structure	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.10		2026-07-28
		12	Use function	Generaltechnicalrequirementsforintravascularultrasound (IVUS)diagnosticequipment YY/T 1659-2019 4.11		2026-07-28
49	Ultrasonic imaging diagnostic equipment	1	All items	Test method for performance of three-dimensional ultrasonography YY/T 1279-2015		2026-07-28
		2	All items	Ultrasonic colour flow imaging systems YY/T 0767-2023		2026-07-28

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50	Ultrasonic physiotherapy equipment	1	All items	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020		2026-07-28
		2	General requirements	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.4		2026-07-28
		3	secondary tip vibration excursion	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.7		2026-07-28
		4	drive frequency	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.8		2026-07-28
		5	drived output acoustic power	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.10		2026-07-28
		6	quiescent electrical power	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.11		2026-07-28
		7	maximum electrical power	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.12		2026-07-28
		8	clamping force	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.13		2026-07-28
		9	grasping force	Medical electrical equipment Part 2-5: Particular requirements for the basic safety and essential performance of Ultrasonic physiotherapy equipment GB 9706.205-2020 201.15		2026-07-28
		10	All items	Medical electrical equipment Part 2-5: GB Particular requirements for the safety of ultrasonic physiotherapy equipmen GB 9706.7-2008	For use only when referenced	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					or as stipulated in special contracts	
				Medical electrical equipment Part 2-5: GB Particular requirements for the safety of ultrasonic physiotherapy equipmen IEC 60601-2-5:2000		2026-07-28
		11	All items	Ultrasonic Therapy Equipment for Superficial Tissue YY 0830-2011		2026-07-28
		12	Part of Items	Ultrasonics-surgical systems-Measurement and declaration of the basic output characteristics YY/T 0644-2008	Except for 6.5、6.6	2026-07-28
		13	All items	Ultrasonic physiotherapy equipment YY /T 1090-2018		2026-07-28
51	Ultrasonic surgical equipment for soft tissue excision and hemostasia	1	All items	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020		2026-07-28
		2	primary tip vibration excursion	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.1		2026-07-28
		3	secondary tip vibration excursion	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.2		2026-07-28
		4	drive frequency	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.3		2026-07-28
		5	drived output acoustic power	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.4		2026-07-28
		6	quiescent electrical power	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.5		2026-07-28
		7	maximum electrical power	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.6		2026-07-28
		8	clamping force	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.7		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	grasping force	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.8		2026-07-28
		10	Appearance and structure	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.9		2026-07-28
		11	Use function	Ultrasonic surgical equipment for soft tissue excision and hemostasia YY/T 1750-2020 4.10		2026-07-28
52	Ultrasonic biometer for ophthalmology	1	All items	Ophthalmic high frequency ultrasound scanner YY/T 0849-2011		2026-07-28
		2	All items	General technical requirements for ophthalmic ultrasound B-mode scan YY/T 0773-2010		2026-07-28
53	A modeultasonic biometerforoph thalmologysca nner	1	All items	A modeultasonicbiometerforophthalmologyscanner YY/T 0107-2024		2026-07-28
		2	Measurement range	A modeultasonicbiometerforophthalmologyscanner YY/T 0107-2024 4.1		2026-07-28
		3	measurement error	A modeultasonicbiometerforophthalmologyscanner YY/T 0107-2024 4.2		2026-07-28
		4	Effective display digits	A modeultasonicbiometerforophthalmologyscanner YY/T 0107-2024 4..3		2026-07-28
		5	additional function	A modeultasonicbiometerforophthalmologyscanner YY/T 0107-2024 4.4		2026-07-28
		6	Internal power supply working time	A modeultasonicbiometerforophthalmologyscanner YY/T 0107-2024 4.5		2026-07-28
		7	Appearance and Structure	A modeultasonicbiometerforophthalmologyscanner YY/T 0107-2024 4.6		2026-07-28
54	Medicalultraso nicnebulizer	1	All items	Medicalultrasonicnebulizer YY/T 0109-2024		2026-07-28
		2	Ultrasonic oscillation frequency deviation	Medicalultrasonicnebulizer YY/T 0109-2024 4.1		2026-07-28
		3	Total amount of	Medicalultrasonicnebulizer YY/T 0109-2024 4.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			ultrasonic atomization			
		4	Maximum ultrasonic atomization rate	Medicalultrasonicnebulizer YY/T 0109-2024 4..3		2026-07-28
		5	water temperature	Medicalultrasonicnebulizer YY/T 0109-2024 4.4		2026-07-28
		6	noise	Medicalultrasonicnebulizer YY/T 0109-2024 4.5		2026-07-28
		7	Distribution characteristics of atomized particles	Medicalultrasonicnebulizer YY/T 0109-2024 4.6		2026-07-28
		8	Maximum liquid capacity warning	Medicalultrasonicnebulizer YY/T 0109-2024 4.7		2026-07-28
		9	control function	Medicalultrasonicnebulizer YY/T 0109-2024 4.8		2026-07-28
		10	Appearance and Structure	Medicalultrasonicnebulizer YY/T 0109-2024 4.9		2026-07-28
		11	accompanying document	Medicalultrasonicnebulizer YY/T 0109-2024 4.10		2026-07-28
55	Ultrasonic imaging diagnostic accessory equipment	1	All items	Test methods for B mode ultrasonic diagnostic equipment :connect the Intracavity probe YY/T 0906-2013		2026-07-28
		2	All items	Medical ultrasonic couplant YY 0299-2022		2026-07-28
56	high frequency surgical equipment	1	All items	Medical electrical equipment—Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories GB 9706.202-2021		2026-07-28
		2	Part of Items	Medical electrical equipment Part2-2:Particular requirements for the safety of high frequency surgical equipment GB 9706.4—	Except for 39；For	2026-07-28

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				2009	use only when referenced or as stipulated in special contracts	
				Medical electrical equipment Part2-3:Particular requirements for the safety of high frequency surgical equipment IEC 60601-2-2:2017+A1:2016+A2:2013+ISH12025	Except for 39	2026-07-28
		3	All items	High frequency electrocautery therapy equipmen YY/T 0322-2018/XGI-2023		2026-07-28
		4	All items	Millimeter wave therapy equipment YY/T 0898-2013		2026-07-28
		5	All items	Specified electromagnetic wave therapy equipment YY/T 0061-2021		2026-07-28
57	short-wave therapy equipment	1	All items	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020		2026-07-28
		2	Genral Requipment	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.4		2026-07-28
		3	Genral Requipments for Testing ME Equipment	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.5		2026-07-28
		4	Classification of ME Equipment and ME Systems	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.6		2026-07-28
		5	ME Equipment Identification，	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave		2026-07-28

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			Marking，and Documents	therapy equipment GB 9706.203-2020 201.7		
		6	Protiction Against Electrical Hazards From ME Equipment	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.8		2026-07-28
		7	Protiction Against Mechannical Hazards of ME Equipment and ME Systems	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.9		2026-07-28
		8	Protiction Against Unwanted and Excessive Radiation Hazards	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.10		2026-07-28
		9	Protiction Against Excessive Temperatures and Other Hazards	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.11		2026-07-28
		10	Accuracy of Controls and Instruments and Protection Against Hazardous Outputs	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.12		2026-07-28
		11	Hazardous Situations and Fault Conditions	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.13		2026-07-28
		12	Programmable Electrical Medical Systems（PEMS）	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.14		2026-07-28

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		13	Construction of ME Equipment	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.15		2026-07-28
		14	ME Systems	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.16		2026-07-28
		15	Electromagnetic Compatibility of ME Equipment and ME Systems	Medical electrical equipment-Part 2-3：Particular requirements for the basic safety and essential performance of short-wave therapy equipment GB 9706.203-2020 201.17		2026-07-28
58	Radio-frequency ablation equipment	1	All items	Radio-frequency ablation equipment for ear, nose and throat YY 0897-2013		2026-07-28
		2	All items	Radio frequency ablation catheter YY/T 0778-2018		2026-07-28
59	Radio frequency hyperthermia equipment	1	all items	Radio frequency hyperthermia equipment YY 0777-2023		2026-07-28
		2	operating frequency	Radio frequency hyperthermia equipment YY 0777-2023 4.1		2026-07-28
		3	output power	Radio frequency hyperthermia equipment YY 0777-2023 4.2		2026-07-28
		4	temperature measurement	Radio frequency hyperthermia equipment YY 0777-2023 4.3		2026-07-28
		5	temperature control	Radio frequency hyperthermia equipment YY 0777-2023 4.4		2026-07-28
		6	function	Radio frequency hyperthermia equipment YY 0777-2023 4.5		2026-07-28
		7	manual	Radio frequency hyperthermia equipment YY 0777-2023 4.6		2026-07-28
		8	Electrical safety	Radio frequency hyperthermia equipment YY 0777-2023 4.7		2026-07-28

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		9	Environmental Test	Radio frequency hyperthermia equipment YY 0777-2023 4.8		2026-07-28
60	Radiofrequencyablationinstrumentforcardiacapplication	1	All items	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024		2026-07-28
		2	Operating Frequency	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.1.1		2026-07-28
		3	RF Output Power	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.1.2		2026-07-28
		4	Impedance display function	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.1.3		2026-07-28
		5	Temperature display function	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.1.4		2026-07-28
		6	Timing	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.1.5		2026-07-28
		7	Protection function	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.1.6		2026-07-28
		8	Equipment appearance	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.1.7		2026-07-28
		9	Manual stop function	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.1.8		2026-07-28
		10	priming pump	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.2		2026-07-28
		11	Cardiac radiofrequency ablation catheter	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.3		2026-07-28
		12	Cardiac Surgery Radiofrequency Ablation Surgical Accessories	Radiofrequencyablationinstrumentforcardiacapplication YY/T 0860-2024 5.4		2026-07-28

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61	General technical requirements for radio frequency ablation equipment	1	All items	General technical requirements for radio frequency ablation equipment YY 0650-2022		2026-07-28
		2	Output waveform parameters	General technical requirements for radio frequency ablation equipment YY 0650-2022 4.2		2026-07-28
		3	RF Output Power	General technical requirements for radio frequency ablation equipment YY 0650-2022 4.3		2026-07-28
		4	Temperature control mode	General technical requirements for radio frequency ablation equipment YY 0650-2022 4.4		2026-07-28
		5	Protection function	General technical requirements for radio frequency ablation equipment YY 0650-2022 4.5		2026-07-28
		6	Other functions	General technical requirements for radio frequency ablation equipment YY 0650-2022 4.6		2026-07-28
62	radio frequency ablation equipment for liver	1	All items	radio frequency ablation equipment for liver YY/T 0776-2023		2026-07-28
		2	Operating Frequency	radio frequency ablation equipment for liver YY/T 0776-2023 4.1		2026-07-28
		3	Operating Frequency	radio frequency ablation equipment for liver YY/T 0776-2023 4.2		2026-07-28
		4	RF Output Power	radio frequency ablation equipment for liver YY/T 0776-2023 4.3		2026-07-28
		5	High current mode	radio frequency ablation equipment for liver YY/T 0776-2023 4.4		2026-07-28
		6	Impedance display function	radio frequency ablation equipment for liver YY/T 0776-2023 4.5		2026-07-28
		7	Temperature display function	radio frequency ablation equipment for liver YY/T 0776-2023 4.6		2026-07-28
		8	Protection function	radio frequency ablation equipment for liver YY/T 0776-2023 4.7		2026-07-28
		9	Timing	radio frequency ablation equipment for liver YY/T 0776-2023 4.8		2026-07-28

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		№	Item/ Parameter			
		10	priming pump	radio frequency ablation equipment for liver YY/T 0776-2023 4.9		2026-07-28
		11	Liver radiofrequency ablation electrode, auxiliary (remote) temperature probe	radio frequency ablation equipment for liver YY/T 0776-2023 4.11		2026-07-28
		12	Neutral electrode	radio frequency ablation equipment for liver YY/T 0776-2023 4.12		2026-07-28
63	Oral treatment equipment	1	All items	Ultrasonics dental descaler equipment YY/T 0460-2009		2026-07-28
		2	All items	Ultrasonics—Dental descaler systems—Measurement and declaration of the output characteristics YY/T 0751-2009		2026-07-28
		3	All items	dentistry—powered polymerization activators—part 1:quartz tungsten halogen lamps YY 0055-2018		2026-07-28
		4	All items	dentistry—dental units—part 2:water and air supply YY/T 1043.2-2018		2026-07-28
		5	All items	dental handpieces—part 1:high-speed air turbine handpieces YY 1045-2021		2026-07-28
		6	All items	Dentistry— Dental implant unit YY/T 1485-2016		2026-07-28
		7	All items	high-speed dental air turbine unit YY/T 1044-2018		2026-07-28
		8	All items	general techonlogy condition for electric dental engine YY/T 1147-2004		2026-07-28
		9	All items	Dentistry - Dental rubber dam technique - Part 1: Hole punch YY/T 1487.1-2016		2026-07-28
		10	All items	Dentistry— Whitening Accelerator YY/T 1401-2016		2026-07-28
		11	All items	Dental Rotary instruments - Nominal diameters and designation code number YY/T 1011-2022		2026-07-28

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		№	Item/ Parameter			
64	Portable dental equipment	1	All items	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025		2026-07-28
		2	General Requirements	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.1		2026-07-28
		3	General Requirements	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.2.1		2026-07-28
		4	Handle or other lifting device	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.2.2		2026-07-28
		5	maximum quality	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.2.3		2026-07-28
		6	Maximum size	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.2.4		2026-07-28
		7	environmental exposure	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.2.5		2026-07-28
		8	impact	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.2.6		2026-07-28
		9	fall	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.2.7		2026-07-28
		10	vibration	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.2.8		2026-07-28

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		11	Particulate matter and liquid ingress during transportation	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.2.9		2026-07-28
		12	flammability	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.2.10		2026-07-28
		13	Assembly and disassembly requirements	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.3		2026-07-28
		14	Public utility requirements	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.4		2026-07-28
		15	Working environment conditions	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.5.1		2026-07-28
		16	usability	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.5.2		2026-07-28
		17	The application part that does not provide calories to patients	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.5.3		2026-07-28
		18	Clean and disinfect the outer surface	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.5.4		2026-07-28
		19	noise	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 5.5.5		2026-07-28

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		№	Item/ Parameter			
		20	Manufacturer's manual	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 8		2026-07-28
		21	mark	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 9		2026-07-28
		22	packaging	Dentistry-Portable dental equipment for use in non-permanent healthcare environment-Part 1:General requirements YY/T 1971.1-2025 10		2026-07-28
65	Dentistry—Stationary dental units and dental patient chairs—Part 1:General requirements	1	All items	Dentistry—Stationary dental units and dental patient chairs—Part 1:General requirements YY/T 1043.1-2022		2026-07-28
		2	Basic safety and basic performance	Dentistry—Stationary dental units and dental patient chairs—Part 1:General requirements YY/T 1043.1-2022 5.1.1		2026-07-28
		3	Controllers and Indicators	Dentistry—Stationary dental units and dental patient chairs—Part 2:General requirements YY/T 1043.1-2022 5.1.2		2026-07-28
		4	Function stop system	Dentistry—Stationary dental units and dental patient chairs—Part 3:General requirements YY/T 1043.1-2022 5.1.3		2026-07-28
		5	usability	Dentistry—Stationary dental units and dental patient chairs—Part 4:General requirements YY/T 1043.1-2022 5.1.4		2026-07-28
		6	Cleaning and disinfection	Dentistry—Stationary dental units and dental patient chairs—Part 5:General requirements YY/T 1043.1-2022 5.1.5		2026-07-28
		7	OVERHEAT	Dentistry—Stationary dental units and dental patient chairs—Part 6:General requirements YY/T 1043.1-2022 5.1.6		2026-07-28
		8	Solid collector	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.1.8		2026-07-28
		9	Silver mercury alloy separator	Dentistry—Stationary dental units and dental patient chairs—Part 8:General requirements YY/T 1043.1-2022 5.1.9		2026-07-28
		10	Liquid absorption protection	Dentistry—Stationary dental units and dental patient chairs—Part 9:General requirements YY/T 1043.1-2022 5.1.10.1		2026-07-28

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		№	Item/ Parameter			
		11	flammability	Dentistry—Stationary dental units and dental patient chairs—Part 10:General requirements YY/T 1043.1-2022 5.1.10.2		2026-07-28
		12	Gas, water, suction, and wastewater systems	Dentistry—Stationary dental units and dental patient chairs—Part 11:General requirements YY/T 1043.1-2022 5.1.11		2026-07-28
		13	Moving parts	Dentistry—Stationary dental units and dental patient chairs—Part 12:General requirements YY/T 1043.1-2022 5.2.1.1		2026-07-28
		14	Pressure vessels and pressure components for gases or liquids	Dentistry—Stationary dental units and dental patient chairs—Part 13:General requirements YY/T 1043.1-2022 5.2.1.2		2026-07-28
		15	Mechanical hazards of faces, corners, and edges	Dentistry—Stationary dental units and dental patient chairs—Part 14:General requirements YY/T 1043.1-2022 5.2.1.3		2026-07-28
		16	Stability of support system	Dentistry—Stationary dental units and dental patient chairs—Part 15:General requirements YY/T 1043.1-2022 5.2.1.4		2026-07-28
		17	Mechanical requirements for dental treatment machines	Dentistry—Stationary dental units and dental patient chairs—Part 16:General requirements YY/T 1043.1-2022 5.2.2		2026-07-28
		18	Maximum patient mass and static load	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.2.3.1		2026-07-28
		19	Headrest stability	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.2.3.2		2026-07-28
		20	Armrest stability	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.2.3.3		2026-07-28
		21	Carrying capacity and vertical lifting capacity	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.2.3.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		22	Tilt and stability	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.2.3.5		2026-07-28
		23	General Electrical Requirements	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.3.1		2026-07-28
		24	Test points for periodic safety checks	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.3.2		2026-07-28
		25	Position limitations of dental patient chairs	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 5.3.3		2026-07-28
		26	Manufacturer's instructions	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 8		2026-07-28
		27	package	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 9		2026-07-28
		28	mark	Dentistry—Stationary dental units and dental patient chairs—Part 7:General requirements YY/T 1043.1-2022 10		2026-07-28
66	Dentistry—Coupling dimensions for handpiece connectors	1	All items	Dentistry—Coupling dimensions for handpiece connectors YY/T 1012-2021		2026-07-28
		2	General requirements	Dentistry—Coupling dimensions for handpiece connectors YY/T 1012-2021 5.1		2026-07-28
		3	size	Dentistry—Coupling dimensions for handpiece connectors YY/T 1012-2021 5.2		2026-07-28
67	Dentistry—Central suction source equipment	1	All items	Dentistry—Central suction source equipment YY/T 0629-2021		2026-07-28
		2	Design	Dentistry—Central suction source equipment YY/T 0629-2021		2026-07-28
		3	Cleaning and disinfection	Dentistry—Central suction source equipment YY/T 0629-2021		2026-07-28
		4	High-volume suction systems	Dentistry—Central suction source equipment YY/T 0629-2021		2026-07-28

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		№	Item/ Parameter			
		5	Medium-volume suction systems	Dentistry—Central suction source equipment YY/T 0629-2021		2026-07-28
		6	Air separator	Dentistry—Central suction source equipment YY/T 0629-2021		2026-07-28
		7	Accessories	Dentistry—Central suction source equipment YY/T 0629-2021		2026-07-28
		8	Noise level	Dentistry—Central suction source equipment YY/T 0629-2021		2026-07-28
		9	Waste disposal	Dentistry—Central suction source equipment YY/T 0629-2021		2026-07-28
		10	Electrical requirements	Dentistry—Central suction source equipment YY/T 0629-2021		2026-07-28
68	Dentistry-Oral suigical scalpel handle	1	all items	Dentistry-Oral suigical scalpel handle YY/T 1965-2025		2026-07-28
		2	shape	Dentistry-Oral suigical scalpel handle YY/T 1965-2025 5.1		2026-07-28
		3	size	Dentistry-Oral suigical scalpel handle YY/T 1965-2025 5.2		2026-07-28
		4	material	Dentistry-Oral suigical scalpel handle YY/T 1965-2025 5.3		2026-07-28
		5	surface	Dentistry-Oral suigical scalpel handle YY/T 1965-2025 5.4		2026-07-28
		6	Repetitive processing tolerance	Dentistry-Oral suigical scalpel handle YY/T 1965-2025 5.5		2026-07-28
		7	hardness	Dentistry-Oral suigical scalpel handle YY/T 1965-2025 5.6		2026-07-28
		8	The firmness of the connection with the blade	Dentistry-Oral suigical scalpel handle YY/T 1965-2025 5.7		2026-07-28
		9	Marking, labeling, and instructions for use	Dentistry-Oral suigical scalpel handle YY/T 1965-2025 7		2026-07-28

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69	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment	1	All items	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020		2026-07-28
		2	Classification of ME equipment and ME system	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020 201.6		2026-07-28
		3	ME equipment identification, marking and documentation	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020 201.7		2026-07-28
		4	Protection of ME equipment against electric shock hazard	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020 201.8		2026-07-28
		5	Protection of ME equipment and ME system against mechanical hazards	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020 201.9		2026-07-28
		6	Dangerous situation and fault status of ME equipment	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment GB 9706.260-2020 201.13		2026-07-28
70	Nerve and Muscle Stimulators	1	All items	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021		2026-07-28
		2	Application conditions	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.4		2026-07-28
		3	General requirements	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.5		2026-07-28

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		№	Item/ Parameter			
		4	classification	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.6		2026-07-28
		5	Identification, marking and documentation	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.7		2026-07-28
		6	Protection against electric shock hazard	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.8		2026-07-28
		7	Protection against mechanical hazards	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.9		2026-07-28
		8	Protection against unnecessary and excessive radiation hazards	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.10		2026-07-28
		9	Protection against extreme temperature and other hazards	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.11		2026-07-28
		10	Accuracy of controller and instrument and protection of dangerous output	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.12		2026-07-28
		11		particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.13		2026-07-28
		12	PEMS	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.14		2026-07-28

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		№	Item/ Parameter			
		13	Structure of me equipment	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.15		2026-07-28
		14	ME system	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.16		2026-07-28
		15	electromagnetic compatibility	particular requirements for the basic safety and essential performance of nerve and muscle stimulators YY 9706.210-2021 201.17		2026-07-28
		16	All items	Medical electrical equipment—part2:--Particular requirements for the safety of nerve and muscle stimulators YY0607-2007	For use only when referenced or as stipulated in special contracts	2026-07-28
				Medical electrical equipment—part2:--Particular requirements for the safety of nerve and muscle stimulators IEC 60601-2-10:1987		2026-07-28
				Medical electrical equipment—part2:--Particular requirements for the safety of nerve and muscle stimulators IEC 60601-2-10：2012+A1:2016+A2:2023		2026-07-28
		17	All items	Test method for messuring output characteristics of the nerve and muscle stimulators YY/T 0696-2021		2026-07-28
		18	All items	Electrodes for nerve and muscle stimulators YY/T 0868-2021		2026-07-28
		19	All items	Interferential current therapy instrument YY/T 0951-2015/XGI-2023		2026-07-28
71	Electric heating moxibustion	1	All items	Electric heating moxibustion equipment YY/T 1490-2016		2026-07-28
		2	Treatment	Electric heating moxibustion equipment YY/T 1490-2016 5.1		2026-07-28

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	equipment		temperature			
		3	Timing function	Electric heating moxibustion equipment YY/T 1490-2016 5.2		2026-07-28
		4	Noise	Electric heating moxibustion equipment YY/T 1490-2016 5.3		2026-07-28
		5	Noise	Electric heating moxibustion equipment YY/T 1490-2016 5.4		2026-07-28
		6	size of moxibustion head and pad	Electric heating moxibustion equipment YY/T 1490-2016 5.5		2026-07-28
		7	Other requirements of moxibustion pad	Electric heating moxibustion equipment YY/T 1490-2016 5.6		2026-07-28
		8	Manual	Electric heating moxibustion equipment YY/T 1490-2016 5.8		2026-07-28
		9	appearance	Electric heating moxibustion equipment YY/T 1490-2016 5.9		2026-07-28
		10	All items	Electroacupuncture therapy device YY 0780-2018		2026-07-28
72	electrical potential therapy equipment	1	All items	electrical potential therapy equipment YY 0649-2016/XG1-2023		2026-07-28
		2	appearance	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.2		2026-07-28
		3	Output voltage	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.3		2026-07-28
		4	OUTPUT FREQUENCY	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.4		2026-07-28
		5	Output voltage stability	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.5		2026-07-28
		6	short-circuit current	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.6		2026-07-28

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		№	Item/ Parameter			
		7	Output overcurrent protection	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.7		2026-07-28
		8	Safety measures for electric field space	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.8		2026-07-28
		9	Safety range of magnetic field space	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.9		2026-07-28
		10	Durability of treatment pads, treatment blankets, and treatment mattresses	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.1		2026-07-28
		11	noise	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.11		2026-07-28
		12	function	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.13		2026-07-28
		13	Electrical safety	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.14		2026-07-28
		14	electromagnetic compatibility	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.15		2026-07-28
		15	environmental test	electrical potential therapy equipment YY 0649-2016/XG1-2023 4.16		2026-07-28
73	Heat treatment equipment	1	All items	Standard performance and safety specification for cryosurgical medical instruments YY/T 0678-2008		2026-07-28
		2	All items	Liquid nitrogen cryosurgical equipment YY/T 0677-2008		2026-07-28
		3	All items	Semiconductor heating and/or cooling therapy equipment YY/T 0998-2015		2026-07-28
		4	Partial items	Temperature control blanket for medical use YY/T 0952-2022	Except for 5.2.4	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	All items	Heating and Magnetic Vibrator Therapeutic Equipment YY/T 0982-2016		2026-07-28
		6	All items	medical electrical equipment-Part 2：particular requirements for the safety of infant radiant warmers YY 9706.221-2021		2026-07-28
		7	Partial items	Contacting far infrared physiotherapy equipment YY/T 0902-2013	Except for 4.2	2026-07-28
		8	All items	Medical heating pad therapy equipment YY/T 0165-2016		2026-07-28
74	heat radiation therapy equipment	1	all items	General technical requirements for heat radiation therapy equipment YY 0306-2023		2026-07-28
		2	Radiation wavelength range	General technical requirements for heat radiation therapy equipment YY 0306-2023 4.1.1		2026-07-28
		3	Maximum Radiated Power Density	General technical requirements for heat radiation therapy equipment YY 0306-2023 4.1.2		2026-07-28
		4	function	General technical requirements for heat radiation therapy equipment YY 0306-2023 4.2		2026-07-28
75	steam therapy apparatus	1	All items	steam therapy apparatus YY/T 1306-2024		2026-07-28
		2	Fumigation temperature	steam therapy apparatus YY/T 1306-2024 5.1		2026-07-28
		3	Fumigation time	steam therapy apparatus YY/T 1306-2024 5.2		2026-07-28
		4	Anti dry burning function	steam therapy apparatus YY/T 1306-2024 5.3		2026-07-28
		5	Safety protection function	steam therapy apparatus YY/T 1306-2024 5.4		2026-07-28
		6	appearance	steam therapy apparatus YY/T 1306-2024 5.5		2026-07-28
		7	manual	steam therapy apparatus YY/T 1306-2024 5.6		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Electrical safety	steam therapy apparatus YY/T 1306-2024 5.7		2026-07-28
		9	electromagnetic compatibility	steam therapy apparatus YY/T 1306-2024 5.8		2026-07-28
		10	environmental test	steam therapy apparatus YY/T 1306-2024 5.9		2026-07-28
76	Magnetic stimulation equipment	1	All items	Magnetic stimulation equipment YY/T 0994-2015		2026-07-28
77	Force therapy equipment	1	All items	Air-bag type sequential external counter-pulsation device GB 10035-2017		2026-07-28
		2	All items	Compression physiotherapy equipment for limbs YY/T 0833-2020		2026-07-28
		3	All items	Elbow,knee joints passive motion equipment YY/T 0997-2015		2026-07-28
		4	All items	Balance evaluation& exercise systems YY/T 1410-2016		2026-07-28
		5	All items	Walk training platform with suspension YY/T 0900-2013		2026-07-28
		6	All items	Electric cervical and lumbar traction therapy device YY/T 0697-2016		2026-07-28
		7	All items	Table, chair and accessories used for electric cervical and lumbar traction therapy device YY/T 1491-2016		2026-07-28
78	Optical radiation safety requirements	1	All items	Optical radiation safety requirements of wearable devices GB/T 41265-2022		2026-07-28
		2	All items	Photobiological safety of lamps and lamp systems GB/T 20145-2006		2026-07-28
		3	All items	Optics and photonics — Operation microscopes — Light hazard from operation microscopes used in ocular surgery YY 1296-2016		2026-07-28

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		4	All items	Safety of laser products-Part9：Compilation of maximum permissible exposure to incoherent optical radiation GB/T 7247.9-2016		2026-07-28
		5	All items	Measuring methods for optical radiation safety classification ofmedical LED equipment YY/T 1534-2017		2026-07-28
79	General requirements for optical radiation safety	1	All items	General requirements for optical radiation safety GB 44703-2024		2026-07-28
		2	Optical radiation safety risk classification	General requirements for optical radiation safety GB 44703-2024 4		2026-07-28
		3	Optical radiation safety risk identification	General requirements for optical radiation safety GB 44703-2024 5		2026-07-28
		4	Optical radiation safety control requirements for products	General requirements for optical radiation safety GB 44703-2024 6		2026-07-28
		5	Product working process safety control requirements	General requirements for optical radiation safety GB 44703-2024 7		2026-07-28
80	Photobiological safety of non-coherent light products Part1: General requirements	1	All items	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024		2026-07-28
		2	Optical radiation hazard	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 4		2026-07-28
		3	Risk classification	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 5		2026-07-28
		4	General evaluation criteria for classification	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 6		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	Continuous light radiation product risk category determination	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 7		2026-07-28
		6	Identification of risk categories for pulsed light radiation products	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 8		2026-07-28
		7	Optical radiation risk identification	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 9		2026-07-28
		8	Optical radiation control measures	Photobiological safety of non-coherent light products Part1: General requirements GB/T 30117.1-2024 10		2026-07-28
81	Medical Optical Radiation Protective Eyewears	1	All items	Medical Light Radiation Protective Eyewears-Evaluation Method-Part1:Decrease of Light Hazard YY/T 0968.1-2014		2026-07-28
		2	All items	Medical Optical Radiation Protective Eyewears-Evaluation Method-Part2:Vision and Color Vision YY/T 0968.2-2014		2026-07-28
82	Medical electrical equipment Part 2-41:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis	1	All items	Medical electrical equipment Part 2-41:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020		2026-07-28
		2	General requirements	Medical electrical equipment Part 2-41:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.4		2026-07-28
		3	ME equipment identification, marking and documentation	Medical electrical equipment Part 2-42:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.7		2026-07-28
		4	Protection of me equipment against electric shock	Medical electrical equipment Part 2-43:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.8		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			hazard (source)			
		5	Protection of ME equipment and me system against mechanical hazards	Medical electrical equipment Part 2-44:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.9		2026-07-28
		6	Protection against unnecessary or excessive radiation hazards (sources)	Medical electrical equipment Part 2-45:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.10		2026-07-28
		7	Protection against stray radiation	Medical electrical equipment Part 2-46:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.11		2026-07-28
		8	Accuracy of controller and instrument and protection of dangerous output	Medical electrical equipment Part 2-47:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.12		2026-07-28
		9	Dangerous situation and fault status of ME equipment	Medical electrical equipment Part 2-48:Particulae requirements for the basic safty and essential performance of surgical luminaires and luminaires for diagnosis YY 9706.241-2020 201.13		2026-07-28
83	Surgical luminaries and luminaries for diagnosis	1	All items	Medical electrical equipment—Part 2-41:Particular requirements for the safety of surgical luminaries and luminaries for diagnosis YY 0627-2008	For use only when referenced or as stipulated in special contracts	2026-07-28

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84	operating tables	1	All items	MedicaI eIectricaI equipment-Part2-46：ParticuIar requirements for the basic safety and essentiaI performance of operating tables YY 9706.246-2023		2026-07-28
		2	All items	Medical electrical equipment-Part 2-46: Particular requirements for the safety of operating tables YY 0570-2013		2026-07-28
				Medical electrical equipment-Part 2-46: Particular requirements for the safety of operating tables IEC60601-2-46:1998		2026-07-28
		3	All items	Electrically powered operating table YY/T 1106-2008		2026-07-28
85	electrically powered operating table	1	All items	electrically powered operating table YY/T 1106-2023		2026-07-28
		2	appearance	electrically powered operating table YY/T 1106-2023 4.1		2026-07-28
		3	Basic dimensions	electrically powered operating table YY/T 1106-2023 4.2		2026-07-28
		4	Basic parameters of a single action	electrically powered operating table YY/T 1106-2023 4.3		2026-07-28
		5	leakage	electrically powered operating table YY/T 1106-2023 4.4		2026-07-28
		6	Movement stability	electrically powered operating table YY/T 1106-2023 4.5		2026-07-28
		7	Table swing amount	electrically powered operating table YY/T 1106-2023 4.6		2026-07-28
		8	install	electrically powered operating table YY/T 1106-2023 4.7		2026-07-28
		9	material	electrically powered operating table YY/T 1106-2023 4.8		2026-07-28
		10	environmental test	electrically powered operating table YY/T 1106-2023 4.9		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	Electrical safety	electrically powered operating table YY/T 1106-2023 4.10		2026-07-28
86	heating devices using blankets, pads or mattresses	1	All items	Medical electrical equipment--Part 2-52：Particular requirements for the basic safety and essential performance of medical beds YY 9706.252-2021		2026-07-28
		2	All items	Medical electrical equipment -Part2 : Particular requirements for the safety ofelectrically operated hospital beds YY 0571-2013	For use only when referenced or as stipulated in special contracts	2026-07-28
		3	All items	Dynamoelectric traction-table YY/T 0697-2016		2026-07-28
		4	All items	General maternity beds YY/T 0045-2013		2026-07-28
		5	All items	Medical electrical equipment- Part 2-35 :Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use YY 9706.235-2021		2026-07-28
87	infusion pumps	1	All items	Medical electrical equipment-Part 2-24:Particular requirements for the basic safety and essential performance of infusion pumps and controllers GB 9706.224-2021		2026-07-28
				Medical electrical equipment — Part 2-24:Particularr equirements for the safety ofinfusion pumps and controller IEC 60601-2-24:2012		2026-07-28
		2	All items	Medical electrical equipment — Part 2-24:Particularr equirements for the safety ofinfusion pumps and controller GB 9706.27-2005	For use only when referenced or as stipulated	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					in special contracts	
				Medical electrical equipment — Part 2-24:Particularr equirements for the safety ofinfusion pumps and controller IEC 60601-2-24:1998		2026-07-28
		3	All items	Electrical Infusion Pump for Ambulatory Use YY/T 1469—2016		2026-07-28
88	Active implant medical device	1	All items	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY/T 0989.5-2022		2026-07-28
		2	All items	Active implantable medical devices Electromagnetic compatibility Implantable cardiac pacemakers Electromagnetic compatibility testing rules for implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023		2026-07-28
		3	All items	Medical electrical equipment-Part 2-31: Padicular requirements for the safet y ofexternal cardiac pacemakers with internal power source YY 9706.231-2023		2026-07-28
		4	All items	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2015		2026-07-28
				Implants for surgery -- Active implantable medical devices -- Part 2 General requirements for safety,marking and for information to be provided by the manufacturer ISO 14708.1-2014		2026-07-28
		5	All items	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2015		2026-07-28
				Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers ISO 14708.2-2019		2026-07-28
		6	All items	ISO 14708-7 2013 Implants for surgery — Active implantable medical devices --Part 7 Particular requirements for cochlear implant systems YY 0989.7-2017		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ISO 14708-7 2013 Implants for surgery — Active implantable medical devices --Part 7 Particular requirements for cochlear implant systems ISO 14708.7-2019		2026-07-28
		7	All items	Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators ISO 14708.3-2017		2026-07-28
		8	All items	Implants for surgery-Active implantable medical devices-Part 6: Particularrequirements for active implantable medical devices intended to treattachyarrhythmia (including implantable defibrillators) YY 0989.6—2016		2026-07-28
		9	All items	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024		2026-07-28
		10	General requirements for active implantable parts	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 5		2026-07-28
		11	General arrangement of the packaging	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 7		2026-07-28
		12	General markings for active implantable medical devices	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 8		2026-07-28
		13	Markings on the sales packaging	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 9		2026-07-28
		14	Construction of the sales packaging	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 10		2026-07-28

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SCHEDULE OF ACCREDITATION(ANNEX TO CERTIFICATE)

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		15	Markings on the sterile pack	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 11		2026-07-28
		16	Construction of the non-reusable pack	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 12		2026-07-28
		17	Markings on the active implantable medical device	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 13		2026-07-28
		18	Protection from unintentional biological effects being caused by the active implantable medical device	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 14		2026-07-28
		19	Protection from harm to the patient or user caused by external physical features of the active implantable medical device	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 15		2026-07-28
		20	Protection from harm to the patient caused by electricity	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 16		2026-07-28
		21	Protection from harm to the patient caused by heat	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 17		2026-07-28
		22	Protection from ionizing radiation	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			released or emitted from the active implantable medical device	be provided by the manufacturer GB 16174.1-2024 18		
		23	Protection from unintended effects caused by the active implantable medical device	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 19		2026-07-28
		24	Protection of the active implantable medical device from damage caused by external defibrillators	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 20		2026-07-28
		25	Protection of the active implantable medical device from changes caused by electrical fields applied directly to the patient	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 21		2026-07-28
		26	Protection of the active implantable medical device from changes caused by miscellaneous medical treatments	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 22		2026-07-28
		27	Protection of the active implantable	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to		2026-07-28

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SCHEDULE OF ACCREDITATION ATTACHMENT

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			medical device from mechanical forces	be provided by the manufacturer GB 16174.1-2024 23		
		28	Protection of the active implantable medical device from damage caused by electrostatic discharge	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 24		2026-07-28
		29	Protection of the active implantable medical device from damage caused by atmospheric pressure changes	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 25		2026-07-28
		30	Protection of the active implantable medical device from damage caused by temperature changes	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 26		2026-07-28
		31	Protection of the active implantable medical device from electromagnetic non-ionizing radiation	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 27		2026-07-28
		32	Accompanying documentation	Implants for surgery -- Active implantable medical devices -- Part 1 General requirements for safety,marking and for information to be provided by the manufacturer GB 16174.1-2024 28		2026-07-28
		33	All items	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		34	Measurement of IMPLANTABLE PULSE GENERATOR characteristics	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 6.1		2026-07-28
		35	Measurement of the electrical characteristics of a LEAD	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 6.2		2026-07-28
		36	Markings on the sales packaging	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 9		2026-07-28
		37	Markings on the sterile pack	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 11		2026-07-28
		38	Markings on the active implantable medical device	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 13		2026-07-28
		39	Protection from harm to the patient caused by electricity	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 16		2026-07-28
		40	Protection from harm to the patient caused by heat	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 17		2026-07-28
		41	Protection from unintended effects caused by the device	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 19		2026-07-28
		42	Protection of the active implantable medical device from mechanical forces	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 23		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		43	Protection of the active implantable medical device from damage caused byatmospheric pressure changes	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 25		2026-07-28
		44	Accompanying documentation	Implants for surgery -- Active implantable medical devices -- Part 2 Cardiac pacemakers GB 16174.2-2024 28		2026-07-28
89	active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)	1	All Parameters	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025		2026-07-28
		2	Measurement of characteristics of implantable pulse generators and electrode leads	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 6		2026-07-28
		3	Overall design of packaging	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 7		2026-07-28
		4	Universal identification of active implantable medical devices	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 8		2026-07-28
		5	Markings on the sales packaging	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 9		2026-07-28
		6	Construction of	Implants for surgery-Active implantable medical devices-Part 6:		2026-07-28

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			sales packaging	Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 10		
		7	Identification of active implantable medical devices	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 11		2026-07-28
		8	Construction of non-reusable packaging	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 12		2026-07-28
		9	Identification of active implantable medical devices	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 13		2026-07-28
		10	Protection against unexpected biological reactions of active implantable medical devices	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 14		2026-07-28
		11	Protection against harm to patients or users caused by the external physical characteristics of active implantable medical devices	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 15		2026-07-28
		12	Protection against harm caused by	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices		2026-07-28

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SCHEDULE OF ACCREDITATION SIGNIFICANTS

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			electric current to patients	intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 16		
		13	Protection against thermal injury to patients	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 17		2026-07-28
		14	Protection against ionizing radiation released or emitted by active implantable medical devices	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 18		2026-07-28
		15	Protection against unintended use caused by active implantable medical devices	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 19		2026-07-28
		16	Protection of active implantable medical devices from damage caused by external defibrillators	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 20		2026-07-28
		17	Protection of high-power electric fields directly applied to patients by implanted medical devices from causing changes	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 21		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		18	Protection of active implantable medical devices against changes caused by hybrid medical treatment	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 22		2026-07-28
		19	Protection of active implantable medical devices against mechanical forces	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 23		2026-07-28
		20	Protection of active implantable medical devices against damage caused by electrostatic discharge	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 24		2026-07-28
		21	Protection of active implantable medical devices against damage caused by changes in atmospheric pressure	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 25		2026-07-28
		22	Protection of active implantable medical devices against damage caused by temperature changes	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 26		2026-07-28
		23	Protection of active implantable medical	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			devices against non-ionizing electromagnetic radiation	intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 27		
		24	Check the attached file	Implants for surgery-Active implantable medical devices-Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) YY 0989.6—2025 28		2026-07-28
90	Cardiac Pacemakers-Low-Profile Connectors(IS-1)for Implantable Pacemakers	1	All items	Cardiac Pacemakers-Low-Profile Connectors(IS-1)for Implantable Pacemakers YY/T 0491-2004		2026-07-28
		2	electrode catheter connector	Cardiac Pacemakers-Low-Profile Connectors(IS-1)for Implantable Pacemakers YY/T 0491-2004		2026-07-28
		3	connector cavity	Cardiac Pacemakers-Low-Profile Connectors(IS-1)for Implantable Pacemakers YY/T 0491-2004		2026-07-28
91	Implantable cardiac pacing lead	1	All items	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		2	Physical dimensions	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		3	Appearance	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		4	Measurement of Electrical Characteristic of Electrode Conductor	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		5	Protection against mechanical damage	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		6	Protection against mechanical damage	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		7	X-ray detectability	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28

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SCHEDULE OF ACCREDITATION FOR IMPARTIALITY

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		8	Accelerated Aging Life Experiments	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		9	Chemical performance requirements	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		10	sterilization	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		11	Protection against biological effects	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		12	Packaging and marking	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
		13	Random files	Implantable cardiac pacing lead YY/T 0492-2017		2026-07-28
92	Electrical equipment for measurement,control,and laboratory use	1	All items	Safety requirements for electrical equipment for measurement,control,and laboratory use-Part 1:General requirements GB4793.1-2007		2026-07-28
				Electrical equipment for measurement,control,and laboratory use IEC 61010-1：2001		2026-07-28
				Electrical equipment for measurement,control,and laboratory use IEC 61010-1：2010		2026-07-28
		2	All items	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024		2026-07-28
		3	Marking and documentation	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 5		2026-07-28
		4	Protection against electric shock	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 6		2026-07-28
		5	Protection against mechanical hazards	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 7		2026-07-28
		6	Resistance to mechanical stresses	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 8		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	Protection against the spread of fire	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 9		2026-07-28
		8	Equipment temperature limits and resistance to heat	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 10		2026-07-28
		9	Protection against hazards from fluids	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 11		2026-07-28
		10	Protection against radiation，including laser sources，and against sonic and ultrasonic pressure	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 12		2026-07-28
		11	Protection against liberated and substances，explosion and implosion	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 13		2026-07-28
		12	components and subassemblies	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 14		2026-07-28
		13	Protection by interlocks	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 15		2026-07-28
		14	test method	Safety technical specification fou electrical equipment for measurement，control and laboratory use GB 4793-2024 16		2026-07-28
		15	All items	Safety requirements for electrical equipment for measurement，control and laboratory use-Part1：General requirements GB/T 42125.1-2024		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Tests	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1：General requirements GB/T 42125.1-2024 4		2026-07-28
		17	Marking and documentation	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1：General requirements GB/T 42125.1-2024 5		2026-07-28
		18	Protection against electric shock	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1：General requirements GB/T 42125.1-2024 6		2026-07-28
		19	Protection against mechanical hazards	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1：General requirements GB/T 42125.1-2024 7		2026-07-28
		20	Resistance to mechanical stresses	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1：General requirements GB/T 42125.1-2024 8		2026-07-28
		21	Protection against the spread of fire	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1：General requirements GB/T 42125.1-2024 9		2026-07-28
		22	Equipment temperature limits and resistance to heat	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1：General requirements GB/T 42125.1-2024 10		2026-07-28
		23	Protection against hazards from fluids	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1：General requirements GB/T 42125.1-2024 11		2026-07-28
		24	Protection against radiation, including laser	Safety requirements for electrical equipment for measurement, control and laboratory use-Part1：General requirements GB/T 42125.1-2024 12		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			sources，and against sonic and ultrasonic pressure			
		25	Protection against liberated and substances，explosion and implosion	Safety requirements for electrical equipment for measurement，control and laboratory use-Part1：General requirements GB/T 42125.1-2024 13		2026-07-28
		26	components and subassemblies	Safety requirements for electrical equipment for measurement，control and laboratory use-Part1：General requirements GB/T 42125.1-2024 14		2026-07-28
		27	Protection by interlocks	Safety requirements for electrical equipment for measurement，control and laboratory use-Part1：General requirements GB/T 42125.1-2024 15		2026-07-28
		28	Hazards resulting form application	Safety requirements for electrical equipment for measurement，control and laboratory use-Part1：General requirements GB/T 42125.1-2024 16		2026-07-28
		29	Risk assessment	Safety requirements for electrical equipment for measurement，control and laboratory use-Part1：General requirements GB/T 42125.1-2024 17		2026-07-28
		30	All items	Safety requirements for electrical equipment for measurement，control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024		2026-07-28
		31	Tests	Safety requirements for electrical equipment for measurement，control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		32	Marking and documentation	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 5		2026-07-28
		33	Protection against electric shock	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 6		2026-07-28
		34	Protection against mechanical hazards	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 7		2026-07-28
		35	Resistance to mechanical stresses	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 8		2026-07-28
		36	Protection against the spread of fire	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 9		2026-07-28
		37	Equipment temperature limits and resistance to heat	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 10		2026-07-28
		38	Protection against hazards from fluids	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 11		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		39	Protection against radiation，including laser sources，and against sonic and ultrasonic pressure	Safety requirements for electrical equipment for measurement，control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 12		2026-07-28
		40	Protection against liberated and substances，explosion and implosion	Safety requirements for electrical equipment for measurement，control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 13		2026-07-28
		41	components and subassemblies	Safety requirements for electrical equipment for measurement，control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 14		2026-07-28
		42	Protection by interlocks	Safety requirements for electrical equipment for measurement，control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 15		2026-07-28
		43	Hazards resulting form application	Safety requirements for electrical equipment for measurement，control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 16		2026-07-28
		44	Risk assessment	Safety requirements for electrical equipment for measurement，control and laboratory use-Part2：Particular requirements for laboratory equipment for the heating of materials GB/T 42125.2-2024 17		2026-07-28
		45	All items	Safety requirements for electrical equipment for measurement，control and laboratory use-Part3：Particular requirements for		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				refrigerating equipment GB/T 42125.3-2024		
		46	Tests	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 4		2026-07-28
		47	Marking and documentation	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 5		2026-07-28
		48	Protection against electric shock	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 6		2026-07-28
		49	Protection against mechanical hazards	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 7		2026-07-28
		50	Resistance to mechanical stresses	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 8		2026-07-28
		51	Protection against the spread of fire	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 9		2026-07-28
		52	Equipment temperature limits and resistance to heat	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 10		2026-07-28
		53	Protection against hazards from fluids	Safety requirements for electrical equipment for measurement, control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 11		2026-07-28
		54	Protection against radiation，	Safety requirements for electrical equipment for measurement，		2026-07-28

CHINA NATIONAL ACCREDITATION SERVICE FOR CONFORMITY ASSESSMENT
SCHEDULE OF ACCREDITATION ATTACHED TO

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			including laser sources，and against sonic and ultrasonic pressure	control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 12		
		55	Protection against liberated and substances，explosion and implosion	Safety requirements for electrical equipment for measurement，control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 13		2026-07-28
		56	components and subassemblies	Safety requirements for electrical equipment for measurement，control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 14		2026-07-28
		57	Protection by interlocks	Safety requirements for electrical equipment for measurement，control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 15		2026-07-28
		58	Hazards resulting form application	Safety requirements for electrical equipment for measurement，control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 16		2026-07-28
		59	Risk assessment	Safety requirements for electrical equipment for measurement，control and laboratory use-Part3：Particular requirements for refrigerating equipment GB/T 42125.3-2024 17		2026-07-28
		60	All items	Safety requirements for electrical equipment for measurement，control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024		2026-07-28
		61	Tests	Safety requirements for electrical equipment for measurement，control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		62	Marking and documentation	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 5		2026-07-28
		63	Protection against electric shock	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 6		2026-07-28
		64	Protection against mechanical hazards	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 7		2026-07-28
		65	Resistance to mechanical stresses	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 8		2026-07-28
		66	Protection against the spread of fire	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 9		2026-07-28
		67	Equipment temperature limits and resistance to heat	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 10		2026-07-28
		68	Protection against hazards from fluids	Safety requirements for electrical equipment for measurement, control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 11		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		69	Protection against radiation，including laser sources，and against sonic and ultrasonic pressure	Safety requirements for electrical equipment for measurement，control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 12		2026-07-28
		70	Protection against liberated and substances，explosion and implosion	Safety requirements for electrical equipment for measurement，control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 13		2026-07-28
		71	components and subassemblies	Safety requirements for electrical equipment for measurement，control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 14		2026-07-28
		72	Protection by interlocks	Safety requirements for electrical equipment for measurement，control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 15		2026-07-28
		73	Hazards resulting form application	Safety requirements for electrical equipment for measurement，control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 16		2026-07-28
		74	Risk assessment	Safety requirements for electrical equipment for measurement，control and laboratory use-Part4：Particular requirements for climatc and environment testing and other temperature conditioning equipment GB/T 42125.4-2024 17		2026-07-28
		75	All items	Safety requirements for electrical equipment for measurement，control and laboratory use-Part5：Particular requirements for		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				laboratory centrifuges GB/T 42125.5-2024		
		76	Tests	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 4		2026-07-28
		77	Marking and documentation	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 5		2026-07-28
		78	Protection against electric shock	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 6		2026-07-28
		79	Protection against mechanical hazards	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 7		2026-07-28
		80	Resistance to mechanical stresses	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 8		2026-07-28
		81	Protection against the spread of fire	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 9		2026-07-28
		82	Equipment temperature limits and resistance to heat	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 10		2026-07-28
		83	Protection against hazards from fluids	Safety requirements for electrical equipment for measurement, control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 11		2026-07-28
		84	Protection against radiation，	Safety requirements for electrical equipment for measurement，		2026-07-28

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SCHEDULE OF ACCREDITATION FOR TESTING

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			including laser sources，and against sonic and ultrasonic pressure	control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 12		
		85	Protection against liberated and substances，explosion and implosion	Safety requirements for electrical equipment for measurement，control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 13		2026-07-28
		86	components and subassemblies	Safety requirements for electrical equipment for measurement，control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 14		2026-07-28
		87	Protection by interlocks	Safety requirements for electrical equipment for measurement，control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 15		2026-07-28
		88	Hazards resulting form application	Safety requirements for electrical equipment for measurement，control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 16		2026-07-28
		89	Risk assessment	Safety requirements for electrical equipment for measurement，control and laboratory use-Part5：Particular requipments for laboratory centrifuges GB/T 42125.5-2024 17		2026-07-28
		90	All items	Safety requirements for electrical for measurement control and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials GB 4793.6-2008		2026-07-28
				Safety requirements for electrical for measurement control and laboratory use - Part 6: Particular requirements for laboratory equipment for the heating of materials IEC 61010-2-010:2019		2026-07-28
		91	All items	Safety requirements for electrical equipment for measurement control and laboratory use - Part 3: Particular requirements for		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				laboratory equipment for mixing and stirring GB 4793.3-2008		
				Safety requirements for electrical equipment for measurement control and laboratory use - Part 3: Particular requirements for laboratory equipment for mixing and stirring IEC 61010-2-051:2018		2026-07-28
		92	All items	Safety requirements for electrical equipment for measurement, control and laboratory use-Part2-101:Particular requirements for in vitro diagnostic(IVD)medical equipment YY 0648-2008		2026-07-28
		93	All items	Safety requirement for electrical equipment for measurement,control and laboratory use-Particular requirement for autoclaves using steam for the treatment of medical materials and for laboratory process GB 4793.4-2019		2026-07-28
		94	All items	General requirements for in vitro diagnostic medical for self-testing YY/T 1454-2016		2026-07-28
93	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	1	All items	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025		2026-07-28
		2	Test	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-102: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 4		2026-07-28
		3	Markings and Documents	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-103: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 5		2026-07-28
		4	Protection against Electric Shock	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-104: Particular requirements for in vitro diagnostic (IVD) medical equipment		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				YY/T 0648-2025 6		
		5	Protection against Mechanical Hazards	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-105: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 7		2026-07-28
		6	Mechanical stress resistance	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-106: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 8		2026-07-28
		7	Protection against Flame Spread	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-107: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 9		2026-07-28
		8	Temperature Limits and Heat Resistance of Equipment	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-108: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 10		2026-07-28
		9	Protection against hazards of liquids and solid foreign objects	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-109: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 11		2026-07-28
		10	Protection against Radiation (Including Laser Sources), Acoustic Pressure and Ultrasonic Pressure	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-110: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 12		2026-07-28
		11	Protection against released gases and substances	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-111: Particular requirements for in vitro diagnostic (IVD) medical equipment		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				YY/T 0648-2025 13		
		12	Components and Component	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-112: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 14		2026-07-28
		13	Protection by Interlocking Devices	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-113: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 15		2026-07-28
		14	Hazards caused by application	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-113: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 16		2026-07-28
		15	Risk assessment	Safety requirements for electrical equipment for measurement,control and laboratory use-Part 2-113: Particular requirements for in vitro diagnostic (IVD) medical equipment YY/T 0648-2025 17		2026-07-28
94	Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes	1	All items	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023		2026-07-28
		2	Identification and documentation	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 5		2026-07-28
		3	Protection against electric shock	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				6		
		4	Protection against mechanical hazards	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 7		2026-07-28
		5	Resistance to mechanical stress	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 8		2026-07-28
		6	Prevent flame spread	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 9		2026-07-28
		7	Temperature limits and heat resistance of equipment	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 10		2026-07-28
		8	Prevent the danger of fluid and solid foreign objects	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 11		2026-07-28
		9	Protection against radiation (including laser sources), sound pressure and	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			ultrasonic pressure	12		
		10	Protection against released gases and substances, explosions and implosions	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 13		2026-07-28
		11	Components and assemblies	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 14		2026-07-28
		12	Protection with interlocking devices	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 15		2026-07-28
		13	Application hazards	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 16		2026-07-28
		14	Risk assessment	Safety requirement for electrical equipment for measurement,control and laboratory use-Part 14:Particular requirement for automatic and semi-automatic laboratory equipment for analysis and other purposes GB/T 42125.14-2023 17		2026-07-28
				Safety requirements for electrical equipment for measurement, control and laboratory use—Part 9: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes IEC 61010-2-081:2019		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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95	quantitative real-time polymerase chain reaction analyzer	1	All items	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer GB/T 42753-2023		2026-07-28
		2	Appearance	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer GB/T 42753-2023 5.2		2026-07-28
		3	Temperature control performance	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer GB/T 42753-2023 5.6.1		2026-07-28
		4	Fluorescence detection performance	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer GB/T 42753-2023 5.6.2		2026-07-28
		5	performance of the machine	General principles for performance evaluation of quantitative real-time polymerase chain reaction analyzer GB/T 42753-2023 5.6.3		2026-07-28
96	Moist heat sterilized equipment	1	All items	Safety requirements for electrical equipment for measurement control and laboratory use - Part 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials and for laboratory processes GB 4793.8-2008	For use only when referenced or as stipulated in special contracts	2026-07-28
		2	All items	Low temperature steam and formaldehyde sterilizers for medical purposes YY/T 0679-2016		2026-07-28
		3	Partial items	Portable Mode Steam Sterilizers YY 0504-2016	Except for 5.18	2026-07-28
		4	Partial items	Steam sterilizer - the performance requirements of biosafety YY 1277-2016	Except for 4.1	2026-07-28
		5	All items	Steam generators for medical use YY/T 0791-2018		2026-07-28
		6	All items	Medical plasma virus inactivated device YY/T 1510-2017		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	All items	Dry heat (heated air) sterilizers YY 1275-2016		2026-07-28
97	Chemical disinfection sterilized equipment	1	Partial items	Ethylene oxide sterilizer YY 0503-2016	Except for 5.17.1	2026-07-28
98	Urine analyzer equipment	1	All items	Dry chemistry urine analyzer YY/T 0475-2011		2026-07-28
		2	All items	Urine formed element analyzer(digital imaging automatic identification) YY/T 0996-2015		2026-07-28
		3	All items	Dry chemistry analyzer YY/T 0655—2024		2026-07-28
		4		Dry chemistry analyzer YY/T 0655—2024 5.2		2026-07-28
		5		Dry chemistry analyzer YY/T 0655—2024 5.6.1		2026-07-28
		6		Dry chemistry analyzer YY/T 0655—2024 5.6.2		2026-07-28
		7		Dry chemistry analyzer YY/T 0655—2024 5.6.3		2026-07-28
99	Blood analysis equipment	1	All items	automatic blood coagulation analytical nstrument YY/T 0659-2017/XG1-2022		2026-07-28
		2	All items	Blood rheometer YY/T 1460-2016		2026-07-28
		3	All items	Hematology analyzer YY/T 0653-2017/XG1-2022		2026-07-28
		4	All items	Erythrocyte sedimentation rate tester YY/T 1251-2014		2026-07-28
		5	All items	Flow cytometer YY/T 0588-2017		2026-07-28
		6	All items	Centrifugal blood components separation device YY 1413-2016		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		7	All items	Automatic blood analyzer YY/T 1245-2014		2026-07-28
		8	All items	Glycosylated hemoglobin analyzer YY/T 1246-2014		2026-07-28
		9	All items	Heamoglobin instrument YY/T 0032-2004		2026-07-28
		10	All items	General technical requirements for hemog1obin dry chemistry testing systems YY/T 1150-2009		2026-07-28
		11	All items	Dry Hematology Analyzer(centrifuge method) YY/T 1452—2016		2026-07-28
100	Biochemical analysis equipment	1	All items	Automatic chemistry analyzer YY/T 0654-2017		2026-07-28
		2	All items	Semiautomatic biochemistry analyzer YY/T0014-2005		2026-07-28
		3	All items	In vitro diagnostic test systems- General technical requirements for blood-glucose monitoring systems for self-testing GB/T 19634-2021		2026-07-28
101	Electrolyte analyzer	1	All items	Electrolyte analyzer YY/T 0589-2016		2026-07-28
102	Immunoassay Analysis equipment	1	All items	Automatic Time-resolved Fluorescence Counter YY/T 1533-2017		2026-07-28
		2	All items	Detection system of time-resolved fluoroimmunoassay—Part 1:Semi-auto time-resolved fluoroimmunoassay analyser YY/T 1304.1-2015		2026-07-28
		3	All items	Automatic Luminescence Immunoassay Analyzer YY/T 1155-2019		2026-07-28
		4	All items	Semi-automatic chemiluminescence immunoassay analyzer YY/T 1174-2010		2026-07-28
		5	All items	Polymerase Chain Reaction Analyzer YY/T1173-2010		2026-07-28

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		№	Item/ Parameter			
		6	All items	Fluorescence immunochromatography analyzer YY/T 1792-2021		2026-07-28
103	ELISA analytical instruments	1	All items	ELISA analytical instruments YY/T 1529-2024		2026-07-28
		2	appearance	ELISA analytical instruments YY/T 1529-2024 4.1		2026-07-28
		3	Wavelength accuracy and half-peak width	ELISA analytical instruments YY/T 1529-2024 4.2.1		2026-07-28
		4	Absorbance accuracy	ELISA analytical instruments YY/T 1529-2024 4.2.2		2026-07-28
		5	Linearity	ELISA analytical instruments YY/T 1529-2024 4.2.3		2026-07-28
		6	Absorbance repeatability	ELISA analytical instruments YY/T 1529-2024 4.2.4		2026-07-28
		7	Absorbance stability	ELISA analytical instruments YY/T 1529-2024 4.2.5		2026-07-28
		8	Sensitivity	ELISA analytical instruments YY/T 1529-2024 4.2.6		2026-07-28
		9	Channel difference	ELISA analytical instruments YY/T 1529-2024 4.2.7		2026-07-28
		10	Average liquid residue of the cleaning module	ELISA analytical instruments YY/T 1529-2024 4.2.8		2026-07-28
		11	Filling module accuracy and precision	ELISA analytical instruments YY/T 1529-2024 4.2.9		2026-07-28
		12	Lncubation module temperature accuracy and fluctuation	ELISA analytical instruments YY/T 1529-2024 4.2.10		2026-07-28

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		№	Item/ Parameter			
		13	Repeatability of clinical programs	ELISA analytical instruments YY/T 1529-2024 4.2.11		2026-07-28
		14	Sample carrying contamination	ELISA analytical instruments YY/T 1529-2024 4.2.12		2026-07-28
		15	Software function	ELISA analytical instruments YY/T 1529-2024 4.6		2026-07-28
104	High-throughput gene sequencer	1	All items	High-throughput gene sequencer YY/T 1723-2020		2026-07-28
		2	gene sequencing	High-throughput gene sequencer YY/T 1723-2020 4.1		2026-07-28
		3	throughput of gene sequencing	High-throughput gene sequencer YY/T 1723-2020 4.2		2026-07-28
		4	valid throughput of gene sequencing	High-throughput gene sequencer YY/T 1723-2020 4.3		2026-07-28
		5	read length of gene sequencing	High-throughput gene sequencer YY/T 1723-2020 4.4		2026-07-28
		6	base calling	High-throughput gene sequencer YY/T 1723-2020 4.5		2026-07-28
		7	quality of base calling	High-throughput gene sequencer YY/T 1723-2020 4.6		2026-07-28
		8	high-throughput gene sequencer	High-throughput gene sequencer YY/T 1723-2020 4.7		2026-07-28
105	Colloidal gold immunochromatographic reader	1	All items	Colloidal gold immunochromatographic reader YY/T 1582-2018		2026-07-28
		2	appearance	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.1		2026-07-28
		3	resolution ratio	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.2		2026-07-28
		4	accuracy	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.3		2026-07-28

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		№	Item/ Parameter			
		5	repeatability	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.4		2026-07-28
		6	linearity	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.5		2026-07-28
		7	channel consistency (if applicable)	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.6		2026-07-28
		8	stability	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.7		2026-07-28
		9	function	Colloidal gold immunochromatographic reader YY/T 1582-2018 3.8		2026-07-28
106	mass spectrometers	1	All items	General specification for mass spectrometers GB/T 33864-2017		2026-07-28
		2	appearance	General specification for mass spectrometers GB/T 33864-2017		2026-07-28
		3	mass range	General specification for mass spectrometers GB/T 33864-2017		2026-07-28
		4	mass accuracy	General specification for mass spectrometers GB/T 33864-2017		2026-07-28
		5	mass stability	General specification for mass spectrometers GB/T 33864-2017		2026-07-28
		6	mass resolution	General specification for mass spectrometers GB/T 33864-2017		2026-07-28
		7	limit of detection	General specification for mass spectrometers GB/T 33864-2017		2026-07-28
		8	reproducibility	General specification for mass spectrometers GB/T 33864-2017		2026-07-28
		9	safety	General specification for mass spectrometers GB/T 33864-2017		2026-07-28
		10	transport and transportation storage	General specification for mass spectrometers GB/T 33864-2017		2026-07-28

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		№	Item/ Parameter			
		11	environmental suitability	General specification for mass spectrometers GB/T 33864-2017		2026-07-28
107	liquid chromatography-tandem quadrupole mass spectrometry	1	All items	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
		2	resolution	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
		3	mass range	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
		4	灵敏度	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
		5	linear correlation coefficient	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
		6	mass stability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
		7	mass accuracy	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
		8	Area repeatability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
		9	Qualitative repeatability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
		10	Retention time repeatability	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
		11	scanning speed	Method of performance testing for liquid chromatography-tandem quadrupole mass spectrometry GB/T 35410-2017		2026-07-28
108	Clinical mass spectrometer	1	All items	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021		2026-07-28
		2	appearance	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.2		2026-07-28
		3	mass range	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	mass accuracy and mass resolution	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.4		2026-07-28
		5	scanning speed	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.5		2026-07-28
		6	Accuracy of flow rate of infusion pump	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.6		2026-07-28
		7	Accuracy of autosampler and column incubator	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.7		2026-07-28
		8	Linearity of autosampler	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.8		2026-07-28
		9	sensitivity	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.9		2026-07-28
		10	Precision	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.10		2026-07-28
		11	linear	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.11		2026-07-28
		12	Carryover rate	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.12		2026-07-28
		13	Software	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.13		2026-07-28
		14	environmental test	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.14		2026-07-28
		15	Electrical safety	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.15		2026-07-28
		16	electromagnetic compatibility	Clinical mass spectrometer-Part1：Liquid chromatography-mass spectrometer YY/T 1740.1-2021 4.16		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		17	All items	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024		2026-07-28
		18	appearance	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.2		2026-07-28
		19	Software requirement	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.3		2026-07-28
		20	Mass range	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.4		2026-07-28
		21	Mass resolution	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.5		2026-07-28
		22	Background noise	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.6		2026-07-28
		23	Sensitivity	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.7		2026-07-28
		24	Precision	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.8		2026-07-28
		25	Sample consumption	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.9		2026-07-28
		26	Mass stability	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.10		2026-07-28
		27	Oxide ionization yield	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.11		2026-07-28
		28	Double charged ion production rate	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.12		2026-07-28
		29	Measurement stability	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.13		2026-07-28
		30	Contamination-carrying rate	Clinical mass spectrometer-Part 3：Inductively coupled plasma mass spectrometry YY/T 1740.3-2024 5.14		2026-07-28

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		31	All items	Clinical mass spectrometer-Part 2：Matrix-assisted laser desorption ionization-time of flight mass spectrometer YY/T 1740.2-2021		2026-07-28
		32	All items	High performance liquid chromatography GB/T 26792-2019		2026-07-28
109	Inspection auxiliary equipment	1	All items	Thermostatic water bath YY/T 0086-2020		2026-07-28
		2	All items	Automated blood culture system YY/T 0656-2008		2026-07-28
		3	All items	Electrophoresis device YY 0087-2004		2026-07-28
		4	All items	Medical biochemical incubator YY/T 1641-2018		2026-07-28
		5	All items	Medical freezer YY/T 1757-2021		2026-07-28
		6	All items	Automated feces analyzer YY/T 1745-2021		2026-07-28
		7	All items	Sperm qulity analyzer YY/T 1795-2021		2026-07-28
110	Medical Centrifuge	1	All items	Medical centrifuge YY/T 0657-2017		2026-07-28
111	area fluorescent imaging microarray scanner	1	All items	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28
		2	essential function	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28
		3	stability	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28
		4	Resolution	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28
		5	Lowest limit of detection	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28

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		6	linearity	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28
		7	Location Variation	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28
		8	Dynamic Range	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28
		9	safety	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28
		10	environment test	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28
		11	appearance	Technical requipment of area fluorescent imaging microarray scanner GB/T 33806-2017		2026-07-28
112	Bead-based flow cytometric analyzer	1	All items	Bead-based flow cytometric analyzer YY/T 1967-2025		2026-07-28
		2	Normal operating conditions	Bead-based flow cytometric analyzer YY/T 1967-2025 4.1		2026-07-28
		3	Accuracy and repeatability of sample dispensing system	Bead-based flow cytometric analyzer YY/T 1967-2025 4.2		2026-07-28
		4	Accuracy and fluctuation of temperature control system	Bead-based flow cytometric analyzer YY/T 1967-2025 4.3		2026-07-28
		5	detection system	Bead-based flow cytometric analyzer YY/T 1967-2025 4.4		2026-07-28
		6	Carry-over contamination	Bead-based flow cytometric analyzer YY/T 1967-2025 4.5		2026-07-28
		7	Accuracy of clinical assays	Bead-based flow cytometric analyzer YY/T 1967-2025 4.6		2026-07-28

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		8	Within-run precision of clinical assays	Bead-based flow cytometric analyzer YY/T 1967-2025 4.7		2026-07-28
		9	Main functions of the microarray analyzer	Bead-based flow cytometric analyzer YY/T 1967-2025 4.8		2026-07-28
		10	Appearance	Bead-based flow cytometric analyzer YY/T 1967-2025 4.9		2026-07-28
		11	Environmental Testing	Bead-based flow cytometric analyzer YY/T 1967-2025 4.10		2026-07-28
		12	Electrical Safety	Bead-based flow cytometric analyzer YY/T 1967-2025 4.11		2026-07-28
		13	Electromagnetic Compatibility	Bead-based flow cytometric analyzer YY/T 1967-2025 4.12		2026-07-28
113	Cardiopulmonary bypass systems	1	All items	Cardiopulmonary bypass systems--Centrifugal pump-head YY/T 1739-2020		2026-07-28
		2	Cardiopulmonary bypass systems-Assessment method of red blood cell damage in continuous flow blood pumps	Cardiopulmonary bypass systems-Assessment method of red blood cell damage in continuous flow blood pumps YY/T 1620-2018 5.2.6		2026-07-28
114	Roller blood pump	1	All items	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017		2026-07-28
		2	Appearance and structure of blood pump	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.2		2026-07-28
		3	Constant current performance	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.3		2026-07-28

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		4	Pulsatility	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.4		2026-07-28
		5	Mechanical properties	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.5		2026-07-28
		6	Reflux performance	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.6		2026-07-28
		7	Safety monitoring function	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.7		2026-07-28
		8	Noise	Cardiopulmonary bypass systems-Roller blood pump GB 12260-2017 5.8		2026-07-28
115	Usability test of medical devices	1	All items	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016		2026-07-28
		2	General requirements	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 4.1		2026-07-28
		3	Usability engineering file	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 4.2		2026-07-28
		4	All items	Medical devices-Part 1:Application of usability engineering to medical devices IEC 62366-1:2015		2026-07-28
				Medical devices-Application of usability engineering to medical devices IEC 62366-1:2005 4.2		2026-07-28
		5	Scaling of the Usability Engineering effort	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 4.3		2026-07-28
				Medical devices-Application of usability engineering to medical devices IEC 62366-1:2005 4.3		2026-07-28
		6	Application specification	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.1		2026-07-28
		7	Frequently used functions	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.2		2026-07-28
		8	Identification of hazards and	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.3		2026-07-28

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			hazardous situations related to usability	Medical devices-Application of usability engineering to medical devices IEC 62366-1:2005 5.3		2026-07-28
		9	Primary operating function	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.4		2026-07-28
		10	Usability specification	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.5		2026-07-28
		11	Availability validation plan	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.6		2026-07-28
		12	User interface design and implementation	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.7		2026-07-28
		13	Usability verification	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.8		2026-07-28
		14	Usability validation	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 5.9		2026-07-28
		15	accompanying document	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 6		2026-07-28
		16	Training and materials for training	Medical devices-Application of usability engineering to medical devices YY/T 1474-2016 7		2026-07-28
		17	All items	Medical electrical equipment-Part1-6：General requipments for basic safety and essential performance-Collateral standard：Usability IEC 60601-1-6:2010+A 1:2013+A2:2020		2026-07-28
		18	Conditions for application to ME EQUIPMENT	Medical electrical equipment-Part1-6：General requipments for basic safety and essential performance-Collateral standard：Usability IEC 60601-1-6:2010+A 1:2013+A2:2020 4.1		2026-07-28
		19	USABILITY ENGINEERING PROCESS for ME EQUIPMENT	Medical electrical equipment-Part1-6：General requipments for basic safety and essential performance-Collateral standard：Usability IEC 60601-1-6:2010+A 1:2013+A2:2020 4.2		2026-07-28

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		20	Replacement of requirement given in IEC 62366	Medical electrical equipment-Part1-6：General requipments for basic safety and essential performance-Collateral standard：Usability IEC 60601-1-6:2010+A 1:2013+A2:2020 5		2026-07-28
		21	General requipments	Medical devices-Part 1:Application of usability engineering to medical devices EC 62366-1:2015+Corl：2016+A1：2020 4.1		2026-07-28
		22	Prepare use specification	Medical devices-Part 1:Application of usability engineering to medical devices EC 62366-1:2015+Corl：2016+A1：2020 5.1		2026-07-28
		23	Identify user interface characteristics related to safety and potential use errors	Medical devices-Part 1:Application of usability engineering to medical devices EC 62366-1:2015+Corl：2016+A1：2020 5.2		2026-07-28
		24	Idetify and describe hazard-related use scenarios	Medical devices-Part 1:Application of usability engineering to medical devices EC 62366-1:2015+Corl：2016+A1：2020 5.4		2026-07-28
		25	Select rhe hazard-related use scenarios for summative evaluation	Medical devices-Part 1:Application of usability engineering to medical devices EC 62366-1:2015+Corl：2016+A1：2020 5.5		2026-07-28
		26	Establish user interface specification	Medical devices-Part 1:Application of usability engineering to medical devices EC 62366-1:2015+Corl：2016+A1：2020 5.6		2026-07-28
		27	Establish user interface evaluation plan	Medical devices-Part 1:Application of usability engineering to medical devices EC 62366-1:2015+Corl：2016+A1：2020 5.7		2026-07-28
		28	Perform user intrrface design,implementation and formative	Medical devices-Part 1:Application of usability engineering to medical devices EC 62366-1:2015+Corl：2016+A1：2020 5.8		2026-07-28

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		29	Perform summative evaluation of the usability of the user interface	Medical devices-Part 1:Application of usability engineering to medical devices EC 62366-1:2015+Corl：2016+A1：2020 5.9		2026-07-28
		30	User interface of unknown provenance	Medical devices-Part 1:Application of usability engineering to medical devices EC 62366-1:2015+Corl：2016+A1：2020 5.10		2026-07-28
		31	All items	Medical electrical equipment-Part1-6：General requipments for basic safety and essential performance-Collateral standard：Usability YY/T 9706.106-2021		2026-07-28
		32	Conditions for application to ME EQUIPMENT	Medical electrical equipment-Part1-6：General requipments for basic safety and essential performance-Collateral standard：Usability YY/T 9706.106-2021 4.1		2026-07-28
		33	USABILITY ENGINEERING PROCESS for ME EQUIPMENT	Medical electrical equipment-Part1-6：General requipments for basic safety and essential performance-Collateral standard：Usability YY/T 9706.106-2021 4.2		2026-07-28
		34	Replacement of requirement given inYY/T 1474-2016	Medical electrical equipment-Part1-6：General requipments for basic safety and essential performance-Collateral standard：Usability YY/T 9706.106-2021 5		2026-07-28
116	Magnetic resonance equipment	1	All items	Medical Electrical Equipment for medical imaging-Part 1: Determination of essential image quality parameters YY/T 0482-2022		2026-07-28
		2	SNR	Medical Electrical Equipment for medical imaging-Part 1: Determination of essential image quality parameters YY/T 0482-2022 4.2		2026-07-28
		3	Uniformity	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 4.3		2026-07-28

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		4	Electromagnetic compatibility	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 4.4		2026-07-28
		5	Two dimensional geometric distortion	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 4.5		2026-07-28
		6	Spatila resolution	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 4.6		2026-07-28
		7	artifact	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 4.7		2026-07-28
		8	Constancy test	Medical Electrical Equipment-Part 2-33:Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis YY/T 0482-2022 5		2026-07-28
117	Magnetic Resonance Equipment for Medical Diagnosis	1	All items	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.7		2026-07-28
		2	ACCOMPANYING DOCUMENTS	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.7		2026-07-28
		3	protection form electrical charge	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.8		2026-07-28
		4	protection form mechenial	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY		2026-07-28

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				9706.233-2021 201.9		
		5	Pressure vessels and parts subject to pressure	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.12		2026-07-28
		6	Emergency field shut-down unit	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.15		2026-07-28
		7	Medical device system	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 201.16		2026-07-28
		8	Electromagnetic compatibility	Medical Electrical Equipment-Part 2-33:Particular Requirements for the basic safety and essential performance of Magnetic Resonance Equipment for Medical Diagnosis YY 9706.233-2021 202		2026-07-28
118	Traditional Chinese medicine device	1	All items	Meridian stimulator YY/T 1666-2019		2026-07-28
		2	All items	Electrical resistance detector at acupuncture points equipment YY/T 1661-2019		2026-07-28
119	Traditional Chinese medical device-Tongue features acquisition device	1	All items	Traditional Chinese medical device-Tongue features acquisition device YY/T 1488-2025		2026-07-28
		2	Optics	Traditional Chinese medical device-Tongue features acquisition device YY/T 1488-2025 4.1		2026-07-28
		3	Imaging quality	Traditional Chinese medical device-Tongue features acquisition device YY/T 1488-2025 4.2		2026-07-28
		4	Structure	Traditional Chinese medical device-Tongue features acquisition device YY/T 1488-2025 4.3		2026-07-28

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		5	Function	Traditional Chinese medical device-Tongue features acquisition device YY/T 1488-2025 4.4		2026-07-28
		6	Output Information	Traditional Chinese medical device-Tongue features acquisition device YY/T 1488-2025 4.5		2026-07-28
		7	Instructions for Use	Traditional Chinese medical device-Tongue features acquisition device YY/T 1488-2025 4.6		2026-07-28
120	Pulse graph acquisiton device for traditional chinese medicine	1	All items	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016		2026-07-28
		2	Working Condition	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.1		2026-07-28
		3	Safety limits of mechanical force	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.2		2026-07-28
		4	Accuracy of applied mechanical force	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.3		2026-07-28
		5	Accuracy of pulse pressure	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.4		2026-07-28
		6	Accuracy of pulse rate	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.5		2026-07-28
		7	Pressure relief function	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.6		2026-07-28
		8	Effective geometry of sensor	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.7		2026-07-28
		9	Time constant of dynamic amplifier	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.8		2026-07-28
		10	appearance	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.10		2026-07-28
		11	manual	Pulse graph acquisiton device for traditional chinese medicine YY/T 1489-2016 4.11		2026-07-28
121	Particular requirements	1	All items	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light		2026-07-28

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	for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use			source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021		
		2	Classification of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.6		2026-07-28
		3	ME EQUIPMENT identification, marking and documents .	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.7		2026-07-28
		4	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.8		2026-07-28
		5	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.9		2026-07-28
		6	Protection against unwanted and excessive radiation HAZARDS	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.10		2026-07-28
		7	Protection against excessive temperatures and other HAZARDS	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.11		2026-07-28
		8	Accuracy of controls and instruments and	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring		2026-07-28

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			protection against hazardousoutputs	and cosmetic/aesthetic use YY 9706.257-2021 201.12		
		9	HAZARDOUS SITUATIONS and fault conditions	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.13		2026-07-28
		10	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.14		2026-07-28
		11	Construction of ME EQUIPMENT	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.15		2026-07-28
		12	ME SYSTEMS	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.16		2026-07-28
		13	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use YY 9706.257-2021 201.17		2026-07-28
122	medical robotsf	1	All items	Medical electrical equipment-Part 2-77 :Particular requirements for the basic safety and essentialperformance of robotically assisted surgical equipment YY 9706.277-2023		2026-07-28
		2	All items	Medical electrical equipment-Part 2-78：Particular requirements for the basic safety and essential performance of medical robots for rehabilitation,assessment,compensation or alleviation GB 9706.278-2023		2026-07-28

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		№	Item/ Parameter			
123	Medical powered lower extremity exoskeleton robot	1	All items	Medical powered lower extremity exoskeleton robot YY/T 1973-2025		2026-07-28
		2	Motion Performance	Medical powered lower extremity exoskeleton robot YY/T 1973-2025 4.1		2026-07-28
		3	Working Load	Medical powered lower extremity exoskeleton robot YY/T 1973-2025 4.2		2026-07-28
		4	Static Load Strength	Medical powered lower extremity exoskeleton robot YY/T 1973-2025 4.3		2026-07-28
		5	Fatigue Strength	Medical powered lower extremity exoskeleton robot YY/T 1973-2025 4.4		2026-07-28
		6	Operating Noise	Medical powered lower extremity exoskeleton robot YY/T 1973-2025 4.5		2026-07-28
		7	Endurance Time	Medical powered lower extremity exoskeleton robot YY/T 1973-2025 4.6		2026-07-28
		8	Appearance and Structure	Medical powered lower extremity exoskeleton robot YY/T 1973-2025 4.7		2026-07-28
		9	Functionality	Medical powered lower extremity exoskeleton robot YY/T 1973-2025 4.8		2026-07-28
		10	Other Performances	Medical powered lower extremity exoskeleton robot YY/T 1973-2025 4.9		2026-07-28
		11	Environmental Test	Medical powered lower extremity exoskeleton robot YY/T 1973-2025 4.10		2026-07-28
124	Assisted surgical medical equipment and assisted surgical medical system employing	1	All items	Assisted surgical medical equipment and assisted surgical medical system employing robotictechnology YY/T 1712-2021		2026-07-28
		2	master-slave operationl RA equipment accuracy	Assisted surgical medical equipment and assisted surgical medical system employing robotictechnology YY/T 1712-2021 4.2		2026-07-28
		3	Positioning accuracy of navigation guided	Assisted surgical medical equipment and assisted surgical medical system employing robotictechnology YY/T 1712-2021 4.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	robotictechnology		RA equipment			
		4	maximumspace and effective workspace	Assisted surgical medical equipment and assisted surgical medical system employing robotictechnology YY/T 1712-2021 4.4		2026-07-28
		5	Load carrying capacity of manipulator	Assisted surgical medical equipment and assisted surgical medical system employing robotictechnology YY/T 1712-2021 4.5		2026-07-28
		6	master-slave operationl delay time	Assisted surgical medical equipment and assisted surgical medical system employing robotictechnology YY/T 1712-2021 4.6		2026-07-28
		7	environmental test	Assisted surgical medical equipment and assisted surgical medical system employing robotictechnology YY/T 1712-2021 4.7		2026-07-28
		8	safety requirements	Assisted surgical medical equipment and assisted surgical medical system employing robotictechnology YY/T 1712-2021 4.8		2026-07-28
125	Haemodialysis equipment	1	All items	Medical electrical equipment-Part 2-16: Particular requirements for the basicsafety and essential performance of haemodialysis , haemodiafiltration andhaemofiltration equipment GB 9706.216-2021		2026-07-28
		2	All items	Medical electrical equipment-Part 2-39 : Particular requirements for basicsafety and essential performance of peritoneal dialysis equipment GB 9706.239-2021		2026-07-28
		3	All items	Haemodialysis equipment2010- YY 0054-2010	For use only when referenced or as stipulated in special	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					contracts	
		4	All items	Continuous blood purification equipment YY 0645-2018		2026-07-28
126	Medical device software	1	All items	Medical electrical equipment--Part 1-4:General requirements for safety--collateral standard:programmable electrical medical systems YY/T 0708-2009		2026-07-28
		2	All items	Medical device software--Software life cycle processes YY/T 0664-2020		2026-07-28
		3	All items	Special technical requirements for medical image storage and transmission system software YY/T 1861-2023		2026-07-28
		4	All items	Special technical requirements for coronary artery CT image processing software YY/T 1862-2023		2026-07-28
127	Health software	1	All items	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023		2026-07-28
		2	Health software requirements for products	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023 4		2026-07-28
		3	Health software - software life cycle processes	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023 5		2026-07-28
		4	Health software products validation	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023 6		2026-07-28
		5	Health software product identification and accompanying documents	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023 7		2026-07-28
		6	Post launch activities for health software products	Health software—Part 1:General requirements for product safety GB/T 42984.1-2023 8		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
128	Industrial,scientific and medical robots	1	All items	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2026-07-28
		2	Electrostatic discharge immunity test	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2026-07-28
		3	Electrical fast transient/burst immunity test	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2026-07-28
		4	Surge immunity test	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2026-07-28
		5	conducted disturbances, induced by radio-frequency fields	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2026-07-28
		6	conducted disturbances, induced by radio-frequency fields	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2026-07-28
		7	Power frequency magnetic field immunity	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2026-07-28
		8	Voltage dips, short interruptions and voltage variations	Industrial,scientific and medical robots—Electromagnetic compatibility—Immunity tests GB/T 38326-2019		2026-07-28
		9	CE	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2026-07-28
		10	RE（30MHz～1GHz）	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		11	RE（1GHz~18GHz）	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019		2026-07-28
		12	harmonic current	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019	Except for products with an unmeasured current 16A。	2026-07-28
		13	voltage fluctuations and flicker	Industrial,scientific and medical robots—Electromagnetic compatibility—Emission methods of measurement and limits GB/T 38336-2019	Except for products with an unmeasured current 16A。	2026-07-28
129	Electromagnetic compatibility of electrically powered wheelchairs	1	All items	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012		2026-07-28
		2	CE	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.1、5.4.1		2026-07-28
		3	RE（30MHz~1GHz）	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.2.1、5.3.2、5.4.2		2026-07-28
		4	harmonic current	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.3、5.4.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	voltage fluctuations and flicker	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.4、5.4.4		2026-07-28
		6	Electrostatic discharge immunity test	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.2.2、5.3.5、5.4.5		2026-07-28
		7	RS	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.2.3、5.3.6、5.4.6		2026-07-28
		8	Electrical fast transientburst immunity test	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.7、5.4.7		2026-07-28
		9	Surge immunity test	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.8、5.4.8		2026-07-28
		10	conducted disturbances, induced by radio-frequency fields	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.9、5.4.9		2026-07-28
		11	Voltage dips, short interruptions and voltage variations	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.3.10、5.4.10		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		12	Power frequency magnetic field immunity	Wheelchairs-Part 21:Requirements and test methods for electromagnetic compatibility of eletrically powered wheelchairs and scooters and battery chargers GB/T 18029.21-2012 5.2.4		2026-07-28
130	Medical electrical equipment Electromagnetic compatibility	1	harmonic current	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 16 A per phase GB 17625.1-2022		2026-07-28
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 17 A per phase IEC 61000-3-2:2014	For use only when cited or under special contract provisions.	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	voltage fluctuations and flicker	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility(EMC)-Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection GB/T 17625.2-2007		2026-07-28
				Electromagnetic compatibility(EMC)-Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection IEC 61000-3-3:2013	For use only when cited or under special contract provisions.	2026-07-28
		3	Electrostatic	Medical electrical equipment - Part 1 - 2: General requirements	For use	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			discharge immunity test	for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	only when cited or under special contract provisions.	
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Testing and measuring techniques - Electrostatic discharge immunity test GB/T 17626.2-2018		2026-07-28
				Testing and measuring techniques - Electrostatic discharge immunity test IEC 61000-4-2:2008	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2:	For use only when	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Immunity CISPR 14-2:2015	cited or under special contract provisions.	
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
		4	Electrical fast transient/burst immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Testing and measurement techniques -- Electrical fast transient/burst immunity test GB/T 17626.4-2018		2026-07-28
				Testing and measurement techniques -- Electrical fast transient/burst immunity test IEC 61000-4-4:2012		2026-07-28

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SCHEDULE OF ACCREDITATION FOR TESTING

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
		5	Surge immunity test	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					provisions.	
				Testing and measurement techniques - Surge immunity test GB/T 17626.5-2019		2026-07-28
				Testing and measurement techniques - Surge immunity test IEC 61000-4-5:2014	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
		6	conducted disturbances, induced by radio-frequency fields	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					contract provisions.	
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields GB/T 17626.6-2017		2026-07-28
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-6:2013	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015	For use only when cited or under special	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					contract provisions.	
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
		7	Voltage dips, short interruptions and voltage variations	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests GB/T 17626.11-2023		2026-07-28
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests IEC 61000-4-11：2004	For use only when cited or under	2026-07-28

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SCHEDULE OF ACCREDITED TESTS AND CALIBRATIONS

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					special contract provisions.	
				Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current more than 16 A per phase GB/T 17626.34-2012		2026-07-28
				Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current more than 16 A per phase IEC 61000-4-34:2009		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
		8	Power frequency magnetic field immunity	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Testing and measurement techniques - Power frequency magnetic field immunity test GB/T 17626.8-2006		2026-07-28
				Testing and measurement techniques - Power frequency magnetic field immunity test IEC 61000-4-8:2009		2026-07-28
				Testing and measurement techniques - Power frequency magnetic field immunity test IEC 61000-4-8-2001	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
		9	CE	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					contract provisions.	
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011	For use only when cited or under special contract provisions.	2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019	For use only when cited or under	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					special contract provisions.	
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2025		2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2026-07-28
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015	For use only when cited or under special contract provisions.	2026-07-28
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2026-07-28
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15：2018	For use only when cited or under	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					special contract provisions.	
		10	RE（1GHz~18GHz）	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019	For use only when cited or under special contract provisions.	2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2025		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2026-07-28
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015	For use only when cited or under special contract provisions.	2026-07-28
		11	RE（30MHz~1GHz）	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					under special contract provisions.	
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019	For use only when cited or under special contract provisions.	2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2025		2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2026-07-28
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015	For use only when cited or under special contract	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					provisions.	
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011	For use only when cited or under special contract provisions.	2026-07-28
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2026-07-28
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15：2018	For use only when cited or under special contract provisions.	2026-07-28
		12	RE （9kHz~31MHz）	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					contract provisions.	
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019	For use only when cited or under special contract provisions.	2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2025		2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016	For use only when cited or under special contract provisions.	2026-07-28
				Limits and methods of measurement of radio disturbance		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				characteristics of electrical lighting and similar equipment GB/T 17743-2021		
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15：2018	For use only when cited or under special contract provisions.	2026-07-28
		13	click	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018	For use only when cited or under	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					special contract provisions.	
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011	For use only when cited or under special contract provisions.	2026-07-28
		14	distrubance power	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018	For use only when cited or	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					under special contract provisions.	
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011	For use only when cited or under special contract provisions.	2026-07-28
		15	RS	Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 0505-2012	For use only when cited or under special contract provisions.	2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests YY 9706.102-2021		2026-07-28
				Medical electrical equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility (EMC) -- Part 4-3: Testing and measurement techniques -- Radiated, radio-frequency,		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				electromagnetic field immunity test GB/T 17626.3-2023		
				Electromagnetic compatibility (EMC) -- Part 4-4: Testing and measurement techniques -- Radiated, radio-frequency, electromagnetic field immunity test IEC 61000-4-3:2010	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 3: Immunity CISPR 14-2:2015	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
131	Measurement control and laboratory use—EMC	1	harmonic current	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract provisions.	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第1版)	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 16 A per phase GB 17625.1-2022		2026-07-28
				Electromagnetic compatibility (EMC) -- Part 3-2: Limits -- Limits for harmonic current emissions (equipment input current ≤ 17 A per phase IEC 61000-3-2:2014	For use only when cited or under special contract provisions.	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	voltage fluctuations and flicker	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility(EMC)-Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				current ≤16 A per phase and not subject to conditional connection GB/T 17625.2-2007		
				Electromagnetic compatibility(EMC)-Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection EC 61000-3-3:2013	For use only when cited or under special contract provisions.	2026-07-28
		3	Electrostatic discharge immunity test	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2026-07-28
				Electrical equipment for measurement, control and laboratory use	For use	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				-- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005	only when cited or under special contract provisions.	
				Testing and measuring techniques - Electrostatic discharge immunity test GB/T 17626.2-2018		2026-07-28
				Testing and measuring techniques - Electrostatic discharge immunity test IEC 61000-4-2:2008	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Electrical fast transient/burst immunity test	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005	For use only when cited or under special contract provisions.	2026-07-28
				Testing and measurement techniques -- Electrical fast transient/burst immunity test GB/T 17626.4-2018		2026-07-28
				Testing and measurement techniques -- Electrical fast		2026-07-28

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		№	Item/ Parameter			
				transient/burst immunity test IEC 61000-4-4:2012		
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
		5	Surge immunity test	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)	For use only when cited or under	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					special contract provisions.	
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005	For use only when cited or under special contract provisions.	2026-07-28
				Testing and measurement techniques - Surge immunity test GB/T 17626.5-2019		2026-07-28
				Testing and measurement techniques - Surge immunity test IEC 61000-4-5:2014	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015	For use only when cited or under special	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					contract provisions.	
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
		6	conducted disturbances, induced by radio-frequency fields	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005	For use only when cited or under	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					special contract provisions.	
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields GB/T 17626.6-2017		2026-07-28
				Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-6:2013	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
		7	Voltage dips, short interruptions and voltage variations	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					under special contract provisions.	
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005	For use only when cited or under special contract provisions.	2026-07-28
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests GB/T 17626.11-2023		2026-07-28
				Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests IEC 61000-4-11：2004	For use only when cited or	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					under special contract provisions.	
				Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current more than 16 A per phase GB/T 17626.34-2012		2026-07-28
				Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current more than 16 A per phase IEC 61000-4-34:2009		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity GB/T 4343.2-2020		2026-07-28
				Electromagnetic Compatibility—Requirements For Household Appliances, Electric Tools And Similar Apparatus—Part 2: Immunity CISPR 14-2:2015	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28
		8	Power frequency magnetic field immunity	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					provisions.	
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements IEC 61326-1:2005(第 1 版)	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment GB/T 18268.26-2010		2026-07-28
				Electrical equipment for measurement, control and laboratory use -- EMC requirements -- Part 2-6: Particular requirements -- In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005	For use only when cited or under special contract provisions.	2026-07-28
				Testing and measurement techniques - Power frequency magnetic field immunity test GB/T 17626.8-2006		2026-07-28
				Testing and measurement techniques - Power frequency magnetic field immunity test IEC 61000-4-8:2009		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement GB/T 9254.2-2021		2026-07-28
				Information technology equipment – Immunity characteristics – Limits and methods of measurement CISPR 35:2016		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	CE	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011	For use only when cited or under special contract provisions.	2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019	For use only when cited or under special contract provisions.	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2025		2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2026-07-28
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015	For use only when cited or under special contract provisions.	2026-07-28
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2026-07-28
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15：2018	For use only when cited or under special contract provisions.	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		10	RE（1GHz~18GHz）	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019	For use only when cited or under special contract provisions.	2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2025		2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016	For use only when cited or under special contract provisions.	2026-07-28
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015	For use only when cited or under special contract provisions.	2026-07-28
		11	RE（30MHz~1GHz）	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019	For use only when cited or under special contract provisions.	2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2025		2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement CISPR 11:2016	For use only when cited or	2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					under special contract provisions.	
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement GB/T 9254.1-2021		2026-07-28
				Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 32:2015	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio GB 4343.1-2018	For use only when cited or under special contract provisions.	2026-07-28
				Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emissio CISPR 14-1:2011	For use only when cited or under special contract provisions.	2026-07-28
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				17743-2021		
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15：2018	For use only when cited or under special contract provisions.	2026-07-28
		12	RE（9kHz~31MHz）	Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2010	For use only when cited or under special contract provisions.	2026-07-28
				Electrical equipment for measurement, control and laboratory use – EMC requirements -- Part 1: General requirements GB/T 18268.1-2025		2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2019	For use only when cited or under special contract provisions.	2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of measurement GB 4824-2025		2026-07-28
				Scientific and medical(ISM) radio-frequency equipment-electromagnetic disturbance characteristics-limits and methods of	For use only when	2026-07-28

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		№	Item/ Parameter			
				measurement CISPR 11:2016	cited or under special contract provisions.	
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment GB/T 17743-2021		2026-07-28
				Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment CISPR 15：2018	For use only when cited or under special contract provisions.	2026-07-28
132	radiotherapytreatment planning systems	1	All items	Medical electrical equipment radiotherapytreatment planning systems YY 0637-2013		2026-07-28
133	Artificial Intelligence Medical Device	1	All items	Artificial intelligence medical device—Quality requirements and evaluation—Part 3: General requirements for data annotation YY/T 1833.3-2022		2026-07-28
		2	All items	Artificial intelligence medical device—Computer assisted analysis software for pulmonary images—Algorithm performance test methods YY/T 1858-2022		2026-07-28
		3	All items	Artificial intelligence medical device—Quality requirements and evaluation—Part 2: General requirements for datasets YY/T 1833.2-2022		2026-07-28
		4	All items	IEEE Recommended Practice forthe Quality Management of Datasetsfor Medical Artificial Intelligence IEEE 2801-2022		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		5	All items	Artificial intelligence medical device —— Quality requirement and evaluation ——Part 4: traceability YY/T 1833.4-2023		2026-07-28
		6	Requirement on traceability	Artificial intelligence medical device —— Quality requirement and evaluation ——Part 4: traceability YY/T 1833.4-2023 4		2026-07-28
		7	Evaluation methods	Artificial intelligence medical device —— Quality requirement and evaluation ——Part 4: traceability YY/T 1833.4-2023 5		2026-07-28
		8	All items	Artificial intelligence medical device —— Quality requirement and evaluation—— Part 5: pretraining model YY/T 1833.5-2024		2026-07-28
		9	Documentation for pretraining model	Artificial intelligence medical device —— Quality requirement and evaluation—— Part 5: pretraining model YY/T 1833.5-2024 4		2026-07-28
		10	Quality characteristics for pretraining model	Artificial intelligence medical device —— Quality requirement and evaluation—— Part 5: pretraining model YY/T 1833.5-2024 5		2026-07-28
		11	Evaluation methods	Artificial intelligence medical device —— Quality requirement and evaluation—— Part 5: pretraining model YY/T 1833.5-2024 6		2026-07-28
		12	All items	Artificial intelligence medical device——Specific requirement for datasets: color fundus images of diabetic retinopathy YY/T 1949-2024		2026-07-28
		13	Requirement for dataset manual	Artificial intelligence medical device——Specific requirement for datasets: color fundus images of diabetic retinopathy YY/T 1949-2024 4		2026-07-28
		14	Quality characteristics for dataset	Artificial intelligence medical device——Specific requirement for datasets: color fundus images of diabetic retinopathy YY/T 1949-2024 5		2026-07-28
		15	Evaluation methods	Artificial intelligence medical device——Specific requirement for datasets: color fundus images of diabetic retinopathy YY/T 1949-2024 6		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
134	Computer assisted analysis software fo rcytopathologic images	1	All items	Artificial intelligence medical device-Computer assisted analysis software fo rcytopathologic images-Algorithm performance test methods YY/T 1990-2025		2026-07-28
		2	Requirement for algorithm performance testing	Artificial intelligence medical device-Computer assisted analysis software fo rcytopathologic images-Algorithm performance test methods YY/T 1990-2025 4		2026-07-28
		3	Algorithm performance test methods	Artificial intelligence medical device-Computer assisted analysis software for cytopathologic images-Algorithm performance test methods YY/T 1990-2025 5		2026-07-28
135	Computer assisted analysis software forstroke CT images	1	All items	Artificial intelligence medical device-Computer assisted analysis software forstroke CT images-Algorithm performance test methods YY/T 1991-2025		2026-07-28
		2	Requirement for algorithm performance testing	Artificial intelligence medical device-Computer assisted analysis software forstroke CT images-Algorithm performance test methods YY/T 1991-2025 4		2026-07-28
		3	Algorithm performance test methods	Artificial intelligence medical device-Computer assisted analysis software forstroke CT images-Algorithm performance test methods YY/T 1991-2025 5		2026-07-28
136	software of human embryo preimplantation genetic testing for chromosome aneuploidy analysis	1	All items	software of human embryo preimplantation genetic testing for chromosome aneuploidy analysis YY/T1968-2025 4		2026-07-28
		2	Software Quality Requirements	software of human embryo preimplantation genetic testing for chromosome aneuploidy analysis YY/T1968-2025 4.1		2026-07-28
		3	Analyze quality requirements	software of human embryo preimplantation genetic testing for chromosome aneuploidy analysis YY/T1968-2025 4.2		2026-07-28
137	Cybersecurity for Medical Electrical Equipment	1	All items	Basic Requirements of Cybersecurity for Medical Electrical Equipment YY /T 1843-2022		2026-07-28

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138	Nucleic acid extraction system	1	All items	Nucleic acid extraction system YY/T 1908-2023		2026-07-28
		2	appearance	Nucleic acid extraction system YY/T 1908-2023 4.1		2026-07-28
		3	Sample addition accuracy and repeatability	Nucleic acid extraction system YY/T 1908-2023 4.2		2026-07-28
		4	Motion performance of robotic arm	Nucleic acid extraction system YY/T 1908-2023 4.3		2026-07-28
		5	Temperature control	Nucleic acid extraction system YY/T 1908-2023 4.4		2026-07-28
		6	Surface flux density	Nucleic acid extraction system YY/T 1908-2023 4.5		2026-07-28
		7	Static pressure difference	Nucleic acid extraction system YY/T 1908-2023 4.6		2026-07-28
		8	Ultraviolet lamp	Nucleic acid extraction system YY/T 1908-2023 4.7		2026-07-28
		9	Bead residue	Nucleic acid extraction system YY/T 1908-2023 4.8		2026-07-28
		10	Nucleic acid contamination	Nucleic acid extraction system YY/T 1908-2023 4.9		2026-07-28
		11	Consistency of nucleic acid extraction	Nucleic acid extraction system YY/T 1908-2023 4.10		2026-07-28
		12	Software function	Nucleic acid extraction system YY/T 1908-2023 4.11		2026-07-28
		13	Other functions	Nucleic acid extraction system YY/T 1908-2023 4.12		2026-07-28
139	Digital polymerase chain reaction	1	All items	Digital polymerase chain reaction analysis system YY/T 1918-2023		2026-07-28

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	analysis system	2	Appearance requirement	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.1		2026-07-28
		3	Reaction unit uniformity	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.2		2026-07-28
		4	Temperature control	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.3		2026-07-28
		5	Fluorescence intensity repeatability	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.4		2026-07-28
		6	Fluorescent interference	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.5		2026-07-28
		7	Sample detection accuracy	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.6		2026-07-28
		8	Sample detection repeatability	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.7		2026-07-28
		9	Sample linearity	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.8		2026-07-28
		10	Fluorescence linearity	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.9		2026-07-28
		11	Software function	Digital polymerase chain reaction analysis system YY/T 1918-2023 5.10		2026-07-28
140	Medical carbon dioxide incubator	1	All items	Medical carbon dioxide incubator YY/T 1621-2018		2026-07-28
		2	Working environment conditions	Medical carbon dioxide incubator YY/T 1621-2018 4.1		2026-07-28
		3	Appearance and structure	Medical carbon dioxide incubator YY/T 1621-2018 4.2		2026-07-28
		4	Temperature display and control	Medical carbon dioxide incubator YY/T 1621-2018 4.3		2026-07-28

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			performance			
		5	Carbon dioxide concentration display and control performance	Medical carbon dioxide incubator YY/T 1621-2018 4.4		2026-07-28
		6	Relative humidity control performance	Medical carbon dioxide incubator YY/T 1621-2018 4.5		2026-07-28
		7	Noise	Medical carbon dioxide incubator YY/T 1621-2018 4.6		2026-07-28
		8	Alarm	Medical carbon dioxide incubator YY/T 1621-2018 4.7		2026-07-28
		9	Door opening recovery time	Medical carbon dioxide incubator YY/T 1621-2018 4.8		2026-07-28
		10	Thermal insulating property	Medical carbon dioxide incubator YY/T 1621-2018 4.9		2026-07-28
		11	Prevent the generation of condensate water	Medical carbon dioxide incubator YY/T 1621-2018 4.10		2026-07-28
		12	Over temperature protection	Medical carbon dioxide incubator YY/T 1621-2018 4.11		2026-07-28
141	Oral treatment equipment	1	All items	Dentistry—Operating lights YY/T 1120-2021		2026-07-28
		2	General requirements	Dentistry—Operating lights YY/T 1120-2021 5.1		2026-07-28
		3	Adjustment range of illumination	Dentistry—Operating lights YY/T 1120-2021 5.2.1		2026-07-28
		4	Lighting spot	Dentistry—Operating lights YY/T 1120-2021 5.2.2		2026-07-28
		5	The illuminance on the patient's eyes	Dentistry—Operating lights YY/T 1120-2021 5.2.3		2026-07-28

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		6	Chromaticity uniformity	Dentistry—Operating lights YY/T 1120-2021 5.2.4		2026-07-28
		7	Correlated color temperature	Dentistry—Operating lights YY/T 1120-2021 5.2.5		2026-07-28
		8	Radiation heat inside the spot	Dentistry—Operating lights YY/T 1120-2021 5.2.6		2026-07-28
		9	shadow	Dentistry—Operating lights YY/T 1120-2021 5.2.7		2026-07-28
		10	Color rendering index	Dentistry—Operating lights YY/T 1120-2021 5.2.8		2026-07-28
		11	UV irradiance	Dentistry—Operating lights YY/T 1120-2021 5.2.9		2026-07-28
		12	Compatibility with UV cured repair materials	Dentistry—Operating lights YY/T 1120-2021 5.2.10		2026-07-28
		13	Moving parts	Dentistry—Operating lights YY/T 1120-2021 5.3.1		2026-07-28
		14	Operation control	Dentistry—Operating lights YY/T 1120-2021 5.3.2		2026-07-28
		15	turn round	Dentistry—Operating lights YY/T 1120-2021 5.3.3		2026-07-28
		16	General stability	Dentistry—Operating lights YY/T 1120-2021 5.3.4.1		2026-07-28
		17	Stability after position adjustment	Dentistry—Operating lights YY/T 1120-2021 5.3.4.2		2026-07-28
		18	Control force	Dentistry—Operating lights YY/T 1120-2021 5.3.4.3		2026-07-28
		19	mechanical strength	Dentistry—Operating lights YY/T 1120-2021 5.3.4.4		2026-07-28
		20	Spatter	Dentistry—Operating lights YY/T 1120-2021 5.3.5		2026-07-28

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		21	suspended mass	Dentistry—Operating lights YY/T 1120-2021 5.3.6		2026-07-28
		22	Cleaning and disinfection	Dentistry—Operating lights YY/T 1120-2021 5.4		2026-07-28
		23	Electrical safety requirements	Dentistry—Operating lights YY/T 1120-2021 5.5		2026-07-28
		24	Availability requirements	Dentistry—Operating lights YY/T 1120-2021 5.6		2026-07-28
		25	Manufacturer's instructions	Dentistry—Operating lights YY/T 1120-2021 8		2026-07-28
		26	package	Dentistry—Operating lights YY/T 1120-2021 9		2026-07-28
		27	mark	Dentistry—Operating lights YY/T 1120-2021 10		2026-07-28
142	clinical thermometers for body temperature measurement	1	All items	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023		2026-07-28
		2	General requirements	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.4		2026-07-28
		3	General requirements for ME equipment testing	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.5		2026-07-28
		4	Classification of ME devices and ME systems	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.6		2026-07-28

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		5	ME device identification, labeling, and documentation	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.7		2026-07-28
		6	Protection of ME equipment against electric shock hazards	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.8		2026-07-28
		7	Protection of ME equipment and ME systems against mechanica	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.9		2026-07-28
		8	Protection against unwanted or excessive radiation hazards (sources)	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.10		2026-07-28
		9	Protection against ultra mild and other hazards (sources)	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.11		2026-07-28
		10	Accuracy of controllers and instruments and protection against hazardous outputs	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.12		2026-07-28
		11	Dangerous situations and fault states of ME equipment	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.13		2026-07-28
		12	Programmable	Medical electrical equipment—Part 2-56:Particular requirements		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Medical Electrical Systems (PEMS)	for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.14		
		13	The structure of ME equipment	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.15		2026-07-28
		14	ME system	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.16		2026-07-28
		15	Electromagnetic compatibility of ME equipment and ME systems	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.17		2026-07-28
		16	Laboratory performance requirements	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.101		2026-07-28
		17	Probe, probe cable extension and probe sleeve	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 201.103		2026-07-28
		18	Electromagnetic compatibility requirements and tests	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 202		2026-07-28
		19	usability	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				2023 206		
		20	General requirements, testing, and guidelines for alarm systems in medical electrical equipment and medical electrical systems	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 208		2026-07-28
		21	Requirements for medical electrical equipment and systems used in home care environments	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 211		2026-07-28
		22	Requirements for medical electrical equipment and medical electrical systems used in emergency medical service environments	Medical electrical equipment—Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement YY 9706.256-2023 212		2026-07-28
143	orthopaedic surgical navigation equipment employing robotic	1	All items	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023		2026-07-28
		2	General requirements	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.1		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
	technology	3	robotic manipulator positioning equipment performance	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.2		2026-07-28
		4	tracker performance	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.3		2026-07-28
		5	system performance	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.4		2026-07-28
		6	Installation repeatability	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.5		2026-07-28
		7	protection functions	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.6		2026-07-28
		8	liquid cooling	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.8		2026-07-28
		9	software requirements	Requirements and test methods for orthopaedic surgical navigation equipment employing robotic technology YY/T 1901-2023 4.10		2026-07-28
144	Vascular interventional surgical control system employing robotic technology	1	All items	Vascular interventional surgical control system employing robotic technology YY/T 1994-2025		2026-07-28
		2	Control Performance of Interventional Instruments	Vascular interventional surgical control system employing robotic technology YY/T 1994-2025 4.1		2026-07-28
		3	Force Detection	Vascular interventional surgical control system employing robotic technology YY/T 1994-2025 4.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Adjustment Range of Support Arm	Vascular interventional surgical control system employing robotic technology YY/T 1994-2025 4.3		2026-07-28
		5	Software Functions	Vascular interventional surgical control system employing robotic technology YY/T 1994-2025 4.4		2026-07-28
		6	Safety Functions	Vascular interventional surgical control system employing robotic technology YY/T 1994-2025 4.5		2026-07-28
		7	Fused Display of Third-Party Images	Vascular interventional surgical control system employing robotic technology YY/T 1994-2025 4.6		2026-07-28
		8	Performance of Consumable Components	Vascular interventional surgical control system employing robotic technology YY/T 1994-2025 4.7		2026-07-28
145	Robotically assisted surgery equipment-Summative usability	1	All items	Robotically assisted surgery equipment-Summative usability test methods YY/T 1992-2025		2026-07-28
146	Reliability testing methods for robotically assisted surgical equipments	1	All items	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025		2026-07-28
		2	Evaluation Path Selection Method	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025 4.1		2026-07-28
		3	Path 1: Component-Based Complete Machine Reliability Verification	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025 4.2		2026-07-28
		4	Path 2: Complete Machine Reliability Verification	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025 4..3		2026-07-28
		5	Path 3: Post-Market Reliability	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025 4.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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			Verification			
		6	Selection of Reliability Indicators	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025 5		2026-07-28
		7	Fault Criteria	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025 5.3		2026-07-28
		8	Fault Classification	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025 6.2		2026-07-28
		9	Fault Counting Principles	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025 6.3		2026-07-28
		10	Key Performance of the Complete Machine	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025 7.1		2026-07-28
		11	Key Performance of Components	Reliability testing methods for robotically assisted surgical equipments YY/T 1993-2025 7.2		2026-07-28
147	Intravascular optical coherence tomograph	1	All items	Intravascular optical coherence tomograph YY/T 1895-2023		2026-07-28
		2	light source	Intravascular optical coherence tomograph YY/T 1895-2023 4.1		2026-07-28
		3	resolution	Intravascular optical coherence tomograph YY/T 1895-2023 4.2		2026-07-28
		4	sensitivity	Intravascular optical coherence tomograph YY/T 1895-2023 4.3		2026-07-28
		5	scanning performance	Intravascular optical coherence tomograph YY/T 1895-2023 4.4		2026-07-28
		6	measurement performance	Intravascular optical coherence tomograph YY/T 1895-2023 4.5		2026-07-28
		7	pullback performance	Intravascular optical coherence tomograph YY/T 1895-2023 4.6		2026-07-28

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		№	Item/ Parameter			
		8	intravascular imaging catheter	Intravascular optical coherence tomograph YY/T 1895-2023 4.7		2026-07-28
		9	Connection between catheter connection controller and intravascular imaging catheter	Intravascular optical coherence tomograph YY/T 1895-2023 4.8		2026-07-28
148	LEDs	1	All items	Optical radiation safety of LEDs — Part 1：Safety requirements and classification GB/T 39771.1-2021		2026-07-28
		2	Optical radiation safety limiting value	Optical radiation safety of LEDs — Part 1：Safety requirements and classification GB/T 39771.1-2021 4		2026-07-28
		3	grade classification	Optical radiation safety of LEDs — Part 1：Safety requirements and classification GB/T 39771.1-2021 5		2026-07-28
		4	general requirements	Optical radiation safety of LEDs--Part 2:Measurement methods GB/T 39771.2-2021 4		2026-07-28
		5	Testing requirements	Optical radiation safety of LEDs--Part 2:Measurement methods GB/T 39771.2-2021 5		2026-07-28
		6	measuring method	Optical radiation safety of LEDs--Part 2:Measurement methods GB/T 39771.2-2021 6		2026-07-28
149	NIRS	1	All items	Medical electrical equipment--Part 2-71;Particular requirements for the basicsafety and essential performance of functional near-infrared spectroscopy (NIRS)equipment GB 9706.271-2021		2026-07-28
		2	ESSENTIAL PERFORMANCE	Medical electrical equipment--Part 2-71;Particular requirements for the basicsafety and essential performance of functional near-infrared spectroscopy (NIRS)equipment GB 9706.271-2021 201.4.3		2026-07-28
		3	ME EQUIPMENT identification, marking and documents	Medical electrical equipment--Part 2-71;Particular requirements for the basicsafety and essential performance of functional near-infrared spectroscopy (NIRS)equipment GB 9706.271-2021 201.7.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		4	Protection against electrical HAZARDS from ME EQUIPMENT	Medical electrical equipment--Part 2-71;Particular requirements for the basicsafety and essential performance of functional near-infrared spectroscopy (NIRS)equipment GB 9706.271-2021 201.8		2026-07-28
		5	Performance of FUNCTIONAL NIRS EQUIPMENT	Medical electrical equipment--Part 2-71;Particular requirements for the basicsafety and essential performance of functional near-infrared spectroscopy (NIRS)equipment GB 9706.271-2021 201.12.1.101		2026-07-28
150	Components of electric upper limb	1	All items	Components of electric upper limb GB/T 18027-2021		2026-07-28
		2	General requirement	Components of electric upper limb GB/T 18027-2021		2026-07-28
		3	Major technical performance	Components of electric upper limb GB/T 18027-2021		2026-07-28
		4	Reliability	Components of electric upper limb GB/T 18027-2021		2026-07-28
		5	Reliability	Components of electric upper limb GB/T 18027-2021		2026-07-28
		6	Reliability	Components of electric upper limb GB/T 18027-2021		2026-07-28
		7	Reliability	Components of electric upper limb GB/T 18027-2021		2026-07-28
151	Coronary CT image processing software—Algorithm performance test methods	1	All items	Artificial intelligence medical device—Coronary CT image processing software—Algorithm performance test methods YY/T 1907-2023		2026-07-28
		2	Requirement on algorithm performance testing	Artificial intelligence medical device—Coronary CT image processing software—Algorithm performance test methods YY/T 1907-2023		2026-07-28
		3	Test methods under different application scenario	Artificial intelligence medical device—Coronary CT image processing software—Algorithm performance test methods YY/T 1907-2023		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	Algorithm quality characteristics and test methods	Artificial intelligence medical device—Coronary CT image processing software—Algorithm performance test methods YY/T 1907-2023		2026-07-28
152	Nitrous oxide inhalation sedation and analgesia equipment	1	All items	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T 1873-2023		2026-07-28
		2	general requirements	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T 1873-2023 4		2026-07-28
		3	supply of power	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T 1873-2023 6		2026-07-28
		4	accuracy of controllers and instruments and protection against dangerous outputs	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T 1873-2023 7		2026-07-28
		5	leak	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T 1873-2023 8		2026-07-28
		6	connecting port	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T 1873-2023 9		2026-07-28
		7	additional requirements attached	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T 1873-2023 11		2026-07-28
		8	Identifiers, tags, and files	Anaesthetic and respiratory equipment- Medical endoscopes-Video endoscopes YY/T 1873-2023 12		2026-07-28
153	Spirometers intended for the measurement of time forced expired	1	All items	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021		2026-07-28
		2	electric safety	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 4.1		2026-07-28

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	volumes in humans	3	safety of machinery	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 4.2		2026-07-28
		4	a mark on a scale or display	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.1		2026-07-28
		5	mark recognizability	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.2		2026-07-28
		6	durability of mark	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.3		2026-07-28
		7	marking of spirometer or its packaging	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.4		2026-07-28
		8	operation instruction	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.5		2026-07-28
		9	technical instruction	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 5.6		2026-07-28
		10	measuring range	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 6		2026-07-28
		11	accuracy	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.1		2026-07-28
		12	write time	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.2		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		13	graphic displays aspect ratio	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.3		2026-07-28
		14	Volume record	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.4		2026-07-28
		15	Forced exhalation start	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.5		2026-07-28
		16	Forced expiratory termination	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.6		2026-07-28
		17	linearity	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.7		2026-07-28
		18	repeatability	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.8		2026-07-28
		19	Expiratory impedance	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 7.9		2026-07-28
		20	Effects of a hand-held spirometer or attachment falling	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 8.1		2026-07-28
		21	calibration	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 8.2		2026-07-28
		22	Disassemble and reassemble	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 8.3		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		23	Reusable spirometer and components	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 9.1		2026-07-28
		24	Spirometer and its components require treatment prior to use	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 9.2		2026-07-28
		25	Spirometer and parts in aseptic packaging	Anaesthetic and respiratory equipmenSpirometers intended for the measurement of time forced expired volumes in humans YY/T 1804-2021 9.3		2026-07-28
154	Circulatory support device	1	All items	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023		2026-07-28
		2	General requirements for active implantable medical devices	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 5		2026-07-28
		3	Requirements for particular active implantable medical devices	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 6		2026-07-28
		4	General arrangement of the packaging	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 7		2026-07-28
		5	General markings for active implantable medical devices	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 8		2026-07-28
		6	Markings on the sales packaging	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 9		2026-07-28

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		7	Construction of the sales packaging	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 10		2026-07-28
		8	Markings on the sterile pack	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 11		2026-07-28
		9	Construction of the non-reusable pack	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 12		2026-07-28
		10	Markings on the active implantable medical device	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 13		2026-07-28
		11	Protection from unintentional biological effects being caused by the active implantable medical device	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 14		2026-07-28
		12	Protection from harm to the patient or user caused by external physical features of the active implantable medical device	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 15		2026-07-28
		13	Protection from harm to the patient caused by electricity	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 16		2026-07-28
		14	Protection from harm to the patient caused by heat	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 17		2026-07-28
		15	Protection from ionizing radiation	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 18		2026-07-28

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			released or emitted from the active implantable medical device			
		16	Protection from unintended effects caused by the active implantable medical device	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 19		2026-07-28
		17	Protection of the active implantable medical device from damage caused by external defibrillators	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 20		2026-07-28
		18	Protection of the active implantable medical device from changes caused by electrical fields applied directly to the patient	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 21		2026-07-28
		19	Protection of the active implantable medical device from changes caused by miscellaneous medical treatments	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 22		2026-07-28
		20	Protection of the active implantable	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 23		2026-07-28

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			medical device from mechanical forces			
		21	Protection of the active implantable medical device from damage caused by electrostatic discharge	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 24		2026-07-28
		22	Protection of the active implantable medical device from damage caused by atmospheric pressure changes	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 25		2026-07-28
		23	Protection of the active implantable medical device from damage caused by temperature changes	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 26		2026-07-28
		24	Protection of the active implantable medical device from electromagnetic non-ionizing radiation	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 27		2026-07-28
		25	Accompanying documentation	Implants for surgery Active implantable medical devices Part 5: Circulatory support device YY 0989.3-2023 28		2026-07-28
155	Active implantable medical	1	All items	Active implantable medical devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac		2026-07-28

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	devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices			resynchronization devices YY/T 1874-2023		
		2	0HZ ≤ f ≤3000MHz band test requirements	Active implantable medical devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023 4		2026-07-28
		3	Frequency band above 3000MHz	Active implantable medical devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023 5		2026-07-28
		4	The device is protected from the effects of electromagnetic fields in the therapeutic environment	Active implantable medical devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023 6		2026-07-28
		5	Other attached documents	Active implantable medical devicesElectromagnetic compatibilityEMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices YY/T 1874-2023 7		2026-07-28
156	Extracorporeal circulation and blood treatment equipment	1	All items	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023		2026-07-28
		2	general rule	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023 4		2026-07-28
		3	Modifications and supplements to the corresponding content in GB 9706.1-2020	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023 5		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		4	General requirements	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023 5.1		2026-07-28
		5	ME device identification, labeling, and documentation	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023 5.2		2026-07-28
		6	Protection of ME equipment against electric shocks	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023 5.3		2026-07-28
		7	Protection of ME equipment and ME systems against mechanical hazards	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023 5.4		2026-07-28
		8	Protection against ultra mild and other hazards (sources)	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023 5.5		2026-07-28
		9	Accuracy of controllers and instruments and prevention of hazardous outputs	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023 5.6		2026-07-28
		10	Dangerous situations and fault states of ME equipment	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023 5.7		2026-07-28
		11	The structure of ME equipment	General requirements for the safty of blood/intravenous fluid/Iirrigation fluid warmers YY/T 1856-2023 5.8		2026-07-28
157	Medical magnetic resonance	1	All items	General requirements for medical magnetic resonace equipment YY/T 1840-2023		2026-07-28

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	equipment	2	Image performance	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.1		2026-07-28
		3	Magnet requirements	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.2		2026-07-28
		4	Static magnetic field performance	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.3		2026-07-28
		5	Software requirements	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.4		2026-07-28
		6	Mechanical properties	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.5		2026-07-28
		7	The working stability of the equipment	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.6		2026-07-28
		8	Performance of door control components	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.7		2026-07-28
		9	secure	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.8		2026-07-28
		10	environmental test	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.9		2026-07-28
		11	appearance	General requirements for medical magnetic resonace equipment YY/T 1840-2023 4.10		2026-07-28
158	Cutting tools for osseous tissue ultrasonic surgical euqipment	1	All items	Cutting tools for osseous tissue ultrasonic surgical euqipment YY/T 1853-2022		2026-07-28
		2	Structure and dimensions	Cutting tools for osseous tissue ultrasonic surgical euqipment YY/T 1853-2022 4.1		2026-07-28
		3	performance	Cutting tools for osseous tissue ultrasonic surgical euqipment YY/T 1853-2022 4.2		2026-07-28
		4	appearance	Cutting tools for osseous tissue ultrasonic surgical euqipment YY/T 1853-2022 4.3		2026-07-28

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		№	Item/ Parameter			
		5	work requirements	Cutting tools for osseous tissue ultrasonic surgical euqipment YY/T 1853-2022 4.4		2026-07-28
		6	material quality	Cutting tools for osseous tissue ultrasonic surgical euqipment YY/T 1853-2022 4.5		2026-07-28
		7	adaptability	Cutting tools for osseous tissue ultrasonic surgical euqipment YY/T 1853-2022 4.6		2026-07-28
		8	corrosion resistance	Cutting tools for osseous tissue ultrasonic surgical euqipment YY/T 1853-2022 4.7		2026-07-28
Clean area (room)						
1	laboratory animal - requirements of environment and housing facilities		all parameters	Laboratory animal -Requirements of environment and housing facilities GB 14925-2023		2026-07-28
2	clean room(zone) of the pharmaceutical industry		all parameters	clean room(zone) of the pharmaceutical industry		2026-07-28
3	clean room	1	temperature	Code for design of clean room GB50073-2013 6.1		2026-07-28
		2	relative humidity	Code for design of clean room GB50073-2013 6.1		2026-07-28
		3	static pressure	Code for design of clean room GB50073-2013 6.2		2026-07-28
		4	air flow pattern	Code for design of clean room GB50073-2013 6.3		2026-07-28
		5	airflow velocity	Code for design of clean room GB50073-2013 6.3		2026-07-28

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		6	noise	Code for design of clean room GB50073-2013 4.4		2026-07-28
		7	illumination	Code for design of clean room GB50073-2013 9.2		2026-07-28
		8	air volume	Code for design of clean room GB50073-2013 A.3.1		2026-07-28
		9	air cleanliness	Code for design of clean room GB50073-2013 A.3.5		2026-07-28
		10	air supply volume	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2026-07-28
		11	air volume of room or system	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2026-07-28
		12	room exhaust	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.16		2026-07-28
		13	section wind speed	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2026-07-28
		14	sectional wind speed nonuniformity	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.3		2026-07-28
		15	airflow speed of air supply or specific boundary	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.1		2026-07-28
		16	static pressure	Code for construction and acceptance of cleanroom GB50591-2010 16.2 附录,E.2		2026-07-28
		17	cleanliness of 0.6m after opening	Code for construction and acceptance of cleanroom GB50591-2010 16.2 附录,E.2		2026-07-28
		18	portal airflow velocity	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.2		2026-07-28
		19	concentration of ammonia in room	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.14		2026-07-28

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		№	Item/ Parameter			
		20	cleanliness level	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.4		2026-07-28
		21	temperature	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5		2026-07-28
		22	relative humidity	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5		2026-07-28
		23	temperature and humidity toggle range	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5.2		2026-07-28
		24	regional temperature difference and regional humidity difference	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.5.2		2026-07-28
		25	noise	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.6		2026-07-28
		26	illumination	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.7		2026-07-28
		27	tightness	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 G.2-G.4	only test pressure attenuation method	2026-07-28
		28	air flow pattern	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.12.1		2026-07-28
		29	directional flow	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.12.2		2026-07-28
		30	streamline parallelism	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.12.3		2026-07-28
		31	recovrey time of cleanliness	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.11		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		32	Sedimentation bacteria or phytoplankton	Code for construction and acceptance of cleanroom GB50591-2010 16.2,附录 E.8.2,E.8.3	only test Settlement method	2026-07-28
		33	temperature	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2026-07-28
		34	relative humidity	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2026-07-28
		35	airflow velocity	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2026-07-28
		36	ventilation	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2026-07-28
		37	static pressure	Specification for production management of aseptic medical instruments YY 0033-2000 附录 C		2026-07-28
		38	airborne particles	Specification for production management of aseptic medical instruments YY 0033-2000 附录 A、附录 C		2026-07-28
		39	airborne microbe	Specification for production management of aseptic medical instruments YY 0033-2000 附录 A、附录 C		2026-07-28
		40	settling microbe	Specification for production management of aseptic medical instruments YY 0033-2000 附录 A、附录 C		2026-07-28
4	Class Ⅱ biological safety cabinets	1	appearance	Class Ⅱ biological safety cabinets YY0569-2011 5.1		2026-07-28
		2	structure	Class Ⅱ biological safety cabinets YY0569-2011 5.2		2026-07-28
		3	HEPA completeness	Class Ⅱ biological safety cabinets YY0569-2011 5.4.2		2026-07-28
		4	noise	Class Ⅱ biological safety cabinets YY0569-2011 5.4.3		2026-07-28
		5	illumination	Class Ⅱ biological safety cabinets YY0569-2011 5.4.4		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		6	vibration	Class Ⅱ biological safety cabinets YY0569-2011 5.4.5		2026-07-28
		7	downflow air velocity	Class Ⅱ biological safety cabinets YY0569-2011 5.4.7		2026-07-28
		8	inflow air velocity	Class Ⅱ biological safety cabinets YY0569-2011 5.4.8		2026-07-28
		9	air flow pattern	Class Ⅱ biological safety cabinets YY0569-2011 5.4.9		2026-07-28
		10	temperature rise	Class Ⅱ biological safety cabinets YY0569-2011 5.4.12		2026-07-28
		11	UV lamp	Class Ⅱ biological safety cabinets YY0569-2011 5.4.14		2026-07-28
5	clean bench		all parameters	clean bench JG/T 292-2010		2026-07-28
6	biosafety laboratories	1	minimum negative pressure relative to the atmosphere	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2026-07-28
		2	minimum negative pressure difference of adjacent room	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2026-07-28
		3	cleanliness level	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2026-07-28
		4	minimum number of ventilation	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2026-07-28
		5	temperature	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2026-07-28
		6	relative humidity	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2026-07-28
		7	noise	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2026-07-28

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		8	average illumination	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3		2026-07-28
		9	tightness	Architectural and technical code for biosafety laboratories GB 50346-2011 3.3	only test pressure attenuation method	2026-07-28
7	hospital clean operating department	1	maximum bacterial concentration	Architectural and technical code for hospital clean operating department GB50333-2013 3.0.2,3.0.3	only test Settlement method	2026-07-28
		2	air cleanliness	Architectural and technical code for hospital clean operating department GB50333-2013 3.0.2,3.0.3		2026-07-28
		3	pressure	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2026-07-28
		4	minimum number of ventilation	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2026-07-28
		5	airflow velocity	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2026-07-28
		6	temperature	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2026-07-28
		7	relative humidity	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2026-07-28
		8	minimum fresh air volume	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2026-07-28
		9	noise	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2026-07-28
		10	minimum illumination	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2026-07-28
		11	minimum recovrey time of cleanliness	Architectural and technical code for hospital clean operating department GB50333-2013 4.0.1		2026-07-28

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8	industrial cleanroom	1	temperature	ChP2025 Vol Ⅳ，general rule 9205 Table 1		2026-07-28
		2	relative humidity	ChP2025 Vol Ⅳ，general rule 9205 Table 1		2026-07-28
		3	static pressure	ChP2025 Vol Ⅳ General rule 9205 Table 1		2026-07-28
		4	downflow air velocity	ChP2025 Vol Ⅳ，general rule 9205 Table 1		2026-07-28
		5	air distribution	ChP2025 Vol Ⅳ，general rule 9205 Table 1		2026-07-28
		6	airborne particles	ChP2025 Vol Ⅳ，general rule 9205 Table 3		2026-07-28
		7	phytoplankton	ChP2025 Vol Ⅳ，general rule 9205 Table 5		2026-07-28
		8	Sedimentation bacteria	ChP2025 Vol Ⅳ，general rule 9205 Table 5		2026-07-28
		9	microorganisms on the surfaces	ChP2025 Vol Ⅳ，general rule 9205 Table 5		2026-07-28
		10	filter integrality	ChP2025 Vol Ⅳ，general rule 9205 Table 1		2026-07-28
		11	airborne particles	GMP Appendix 1 Article 48		2026-07-28
		12	phytoplankton	GMP Appendix 1 Article 48		2026-07-28
		13	Sedimentation bacteria	GMP Appendix 1 Article 48		2026-07-28
		14	microorganisms on the surfaces	GMP Appendix 1 Article 48		2026-07-28
		15	static pressure	GMP Article 48		2026-07-28
9	medical class	1	exterior	Guide for the check of medical class Ⅱ biogogical safety		2026-07-28

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	Ⅱ biological safety caninets			cabinets YY/T 1540-2017 5.1		
		2	upstream concentration	Guide for the check of medical class Ⅱ biogogical safety cabinets YY/T 1540-2017 5.2		2026-07-28
		3	Alarm and interlocking system sampeling port	Guide for the check of medical class Ⅱ biogogical safety cabinets YY/T 1540-2017 5.3		2026-07-28
		4	aispeed display	Guide for the check of medical class Ⅱ biogogical safety cabinets YY/T 1540-2017 5.4		2026-07-28
		5	filter integrality	Guide for the check of medical class Ⅱ biogogical safety cabinets YY/T 1540-2017 5.5		2026-07-28
		6	noise	Guide for the check of medical class Ⅱ biogogical safety cabinets YY/T 1540-2017 5.6		2026-07-28
		7	illumination	Guide for the check of medical class Ⅱ biogogical safety cabinets YY/T 1540-2017 5.7		2026-07-28
		8	downflow air velocity	Guide for the check of medical class Ⅱ biogogical safety cabinets YY/T 1540-2017 5.8		2026-07-28
		9	inflow air velocity	Guide for the check of medical class Ⅱ biogogical safety cabinets YY/T 1540-2017 5.9		2026-07-28
		10	air flow pattern	Guide for the check of medical class Ⅱ biogogical safety cabinets YY/T 1540-2017 5.10		2026-07-28
		11	ultraviolet lamp	Guide for the check of medical class Ⅱ biogogical safety cabinets YY/T 1540-2017 5.11		2026-07-28
10	biological safety caninets	1	Appearance	《Biological safety cabinets》 GB 41918-2022 6.1		2026-07-28
		2	Alarm and interlocking system sampeling port	《Biological safety cabinets》 GB 41918-2022 5.3.9		2026-07-28

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		3	filter integrality	《Biological safety cabinets》 GB 41918-2022 6.3.2		2026-07-28
		4	noise	《Biological safety cabinets》 GB 41918-2022 6.3.3		2026-07-28
		5	illumination	《Biological safety cabinets》 GB 41918-2022 6.3.4		2026-07-28
		6	downflow air velocity	《Biological safety cabinets》 GB 41918-2022 6.3.7		2026-07-28
		7	inflow air velocity	《Biological safety cabinets》 GB 41918-2022 6.3.8		2026-07-28
		8	air flow pattern	《Biological safety cabinets》 GB 41918-2022 6.3.9		2026-07-28
11	Cleanroom	1	Airborne Particle Count	Test method for airborne particles in clean room(zone)of thepharmaceutical industry GB/T 16292-2025 6		2026-07-28
		2	Airborne microbe	Test method for airborne microbe in clean room(zone) of thepharmaceutical industy GB/T 16293-2025 8		2026-07-28
		3	Settlingmicrobe	Test method for settling microbe in clean room(zone) of the pharmaceutical industy GB/T 16294-2025 8		2026-07-28
Food						
1	Food	1	Acute oral toxicity test	National food safety standard, Acute oral toxicity test GB 15193.3-2014		2026-07-28
		2	Bacterial reverse mutation test	National food safety standard, Bacterial reverse mutation test GB 15193.4-2014		2026-07-28
		3	Mammalian erythrocyte micronucleus test	National food safety standard, Mammalian erythrocyte micronucleus test GB 15193.5-2014		2026-07-28
		4	Mammalian bone marrow cell chromosome aberration test	National food safety standard, Mammalian bone marrow cell chromosome aberration test GB 15193.6-2014		2026-07-28

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		5	Mice spermatogonial cells or spermatocyte chromosome aberration test	National food safety standard, Mice spermatogonial cells or spermatocyte chromosome aberration test GB 15193.8-2014		2026-07-28
		6	Rodent dominant lethal test	National food safety standard, Rodent dominant lethal test GB 15193.9-2014		2026-07-28
		7	In vitro mammalian cell HGPRT gene mutation test	National food safety standard, In vitro mammalian cell HGPRT gene mutation test GB 15193.12-2014		2026-07-28
		8	Twenty eight days oral toxicity test	National food safety standard, Twenty-eight days oral toxicity test GB 15193.22-2014		2026-07-28
		9	Ninety days oral toxicity test	National food safety standard, Ninety days oral toxicity test GB 15193.13-2015		2026-07-28
		10	Teratogenicity study	National food safety standard, Teratogenicity study GB 15193.14-2015		2026-07-28
		11	Reproductive toxicity test	National food safety standard, Reproductive toxicity test GB 15193.15-2015		2026-07-28
		12	Toxicokinetic test	National food safety standard, Toxicokinetic test GB 15193.16-2014		2026-07-28
		13	Chronic toxicity and carcinogencity combined study	National food safety standard, Chronic toxicity and carcinogencity combined study GB 15193.17-2015		2026-07-28
		14	In vitro mammalian cell TK gene mutation test	National food safety standard, In vitro mammalian cell TK gene mutation test GB 15193.20-2014		2026-07-28
Health Food						
1	Health Food	1	Bacterial reverse mutation test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Its Raw Materials (2020)		2026-07-28

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				National food safety standard, Bacterial reverse mutation test GB 15193.4-2014		2026-07-28
		2	Mammalian erythrocyte micronucleus test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Its Raw Materials (2020)		2026-07-28
				National food safety standard, Mammalian erythocyte micronucleus test GB 15193.5-2014		2026-07-28
		3	Acute oral toxicity test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				National food safety standard, Acute oral toxicity test GB 15193.3-2014		2026-07-28
		4	Mammalian bone marrow cell chromosome aberration test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				National food safety standard, Mammalian bone marrow cell chromosome aberration test GB 15193.6-2014		2026-07-28
		5	Mice spermatogonial cells or spermatocyte chromosome aberration test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				National food safety standard, Mice spermatogonial cells or spermatocyte chromosome aberration test GB 15193.8-2014		2026-07-28
		6	Rodent dominant lethal test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				National food safety standard, Rodent dominant lethal test GB 15193.9-2014		2026-07-28
		7	In vitro mammalian cell HGPRT gene mutation test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				National food safety standard, In vitro mammalian cell HGPRT gene mutation test GB 15193.12-2014		2026-07-28
		8	In vitro mammalian cell TK gene mutation test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				National food safety standard, In vitro mammalian cell TK gene mutation test GB 15193.20-2014		2026-07-28
		9	28 days oral toxicity test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				National food safety standard, Twenty-eight days oral toxicity test GB 15193.22—2014		2026-07-28
		10	90 days oral toxicity test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				National food safety standard, Ninety days oral toxicity test GB15193.13—2015		2026-07-28
		11	Reproductive toxicity test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				National food safety standard, Reproductive toxicity test GB 15193.15-2015		2026-07-28
		12	Toxicokinetic test	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)、National food safety standard, Toxicokinetic test GB 15193.16-2014		2026-07-28
		13	Chronic toxicity and carcinogencity combined study	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				National food safety standard, Chronic toxicity and carcinogencity combined study GB15193.17-2015		2026-07-28
		14	Contribute to enhancing the immune function	Testing & Assessment Methods for Health Food Function ,Method for the Assessment of Contribute to enhancing the immune function (2023)Page 18		2026-07-28
		15	Assisting memory improvement function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Assisting memory improvement function (2023)Page 52		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		16	Contribute to Aassisting Normal blood pressure function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Contribute to assisting Normal blood pressure function (2023)Page 147		2026-07-28
		17	Contribute to sleep improvement function	Testing & Assessment Methods for Health Food Function,Method for the assessment of Contribute to sleep improvement function (2023)Page 72		2026-07-28
		18	Alleviating physical fatigue function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Alleviating physical fatigue function (2023)Page75		2026-07-28
		19	Anoxia endurance function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Anoxia endurance function (2023)Page 81		2026-07-28
		20	Auxiliary protective function against the hazards of ionizing radiation	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Auxiliary protective function against the hazards of ionizing radiation (2023)Page157		2026-07-28
		21	Teratogenicity study	Technical Guidelines for Safety and Toxicology Inspection and Evaluation of the Health Food and Raw Materials (2020)		2026-07-28
				National food safety standard, Teratogenicity study GB15193.14-2015		2026-07-28
		22	Contribute to improve bone density function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Contribute to improve bone density function (2023)Page 88		2026-07-28
		23	Protection against chemical injury of liver function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Protection against chemical injury of liver function (2023)Page 150		2026-07-28
		24	Contribute to assessment of Regulating	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Contribute to assessment of Regulating Gastrointestinal Tract Flora Function (2023)Page 113		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Gastrointestinal Tract Flora Function			
		25	Contribute to Relaxing Bowels and Relieving Constipation function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Contribute to Relaxing Bowels and Relieving Constipation function (2023)Page 124		2026-07-28
		26	Contribute to antioxidative function	Testing & Assessment Methods for Health Food Function,Method for the assessment of Contribute to antioxidative function 2023，Page31		2026-07-28
		27	Assisting the protection of gastric mucosa function	Testing & Assessment Methods for Health Food Function,Method for the assessment of Assisting the protection of gastric mucosa function （2023），Page 128		2026-07-28
		28	Contribute to assisting blood sugar keep function	Testing & Assessment Methods for Health Food Function,Method for the assessment of Contribute to assisting blood sugar keep function （2023），Page 137		2026-07-28
		29	Improve nutritional anemia function	Testing & Assessment Methods for Health Food Function,Method for the assessment of Improve nutritional anemia function （2023），Page 96		2026-07-28
		30	Contribute to maintaining healthy levels of blood lipids (cholesterol / triglycerides)	Testing & Assessment Methods for Health Food Function,Method for the assessment of Contribute to maintaining healthy levels of blood lipids (cholesterol / triglycerides) （2023），Page 132		2026-07-28
		31	Contribute to alleviating lead excretion function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Contribute to alleviating lead excretion function （2023），Page 165		2026-07-28
		32	Contribute to controlling body fat function	Testing & Assessment Methods for Health Food Function,Method for the assessment of contribute to Helps to controlling body fat function （2023），Page 84		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		33	Clear pharynx and moisten throat function	Testing & Assessment Methods for Health Food Function,Method for the assessment of Clear pharynx and moisten throat function （2023）Page 67		2026-07-28
		34	Facilitate digestion function	Testing & Assessment Methods for Health Food Function ,Method for the assessment of Facilitate digestion function (2023)Page 119		2026-07-28
Cosmetics						
1	Cosmetic	1	Acute Oral Toxicity Test	Safety and Technical Standards for Cosmetics,Acute Oral Toxicity Test (2015) Chapter 6,No.2		2026-07-28
		2	Acute Dermal Toxicity Test	Safety and Technical Standards for Cosmetics, Acute Dermal Toxicity Test (2015) Chapter 6,No.3		2026-07-28
		3	Dermal Irritation/Corrosion Test	Safety and Technical Standards for Cosmetics,Dermal Irritation/Corrosion Test (2015) Chapter 6,No.4		2026-07-28
		4	Acute Eye Irritation/Corrosion Test	Safety and Technical Standards for Cosmetics, Acute Eye Irritation/Corrosion Test (2015) Chapter 6,No.5		2026-07-28
		5	Skin Sensitisation Test	Safety and Technical Standards for Cosmetics, Skin Sensitisation Test (2015) Chapter 6,No.6		2026-07-28
		6	Skin Phototoxicity Test	Safety and Technical Standards for Cosmetics, Skin Phototoxicity Test (2015) Chapter 6,No.7		2026-07-28
		7	In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test	Safety and Technical Standards for Cosmetics, In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test (2015) Chapter 6,No.9		2026-07-28
		8	In Vitro Mammalian Cell Gene Mutation Test	Safety and Technical Standards for Cosmetics,In Vitro Mammalian Cell Gene Mutation Test (2015) Chapter 6,No.10		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test	Safety and Technical Standards for Cosmetics,In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test (2015) Chapter 6,No.11		2026-07-28
		10	Mammalian Erythrocyte Micronucleus Test	Safety and Technical Standards for Cosmetics, Mammalian Erythrocyte Micronucleus Test (2015) Chapter 6,No.12		2026-07-28
		11	Testicle Cells Chromosome Aberration Test	Safety and Technical Standards for Cosmetics, Testicle Cells Chromosome Aberration Test (2015) Chapter 6,No.13		2026-07-28
		12	Subchronic Oral Toxicity Test	Safety and Technical Standards for Cosmetics,Subchronic Oral Toxicity Test (2015) Chapter 6,No.14		2026-07-28
		13	Subchronic Dermal Toxicity Test	Safety and Technical Standards for Cosmetics, Subchronic Dermal Toxicity Test (2015) Chapter 6,No.15		2026-07-28
		14	Combined Chronic Toxicity/Carcinogenicity Test	Safety and Technical Standards for Cosmetics, Combined Chronic Toxicity/Carcinogenicity Test (2015) Chapter 6,No.17		2026-07-28
		15	Skin absorption: in vivo method	skin absorption--in vivo method OECD 427(2004)		2026-07-28
		16	Guidelines for the testing of chemicals: 3T3 NRU phototoxicity test	Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 18 Guidelines for the testing of chemicals:3T3 NRU phototoxicity test [Annex, Notice No. 147 of 2016 of the China Food and Drug Administration on the Guidelines for the testing of chemicals:3T3 NRU phototoxicity testinto the Safety and Technical Standards for Cosmetics (2015 Edition)]		2026-07-28
		17	Skin Photoallergy Test	Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 20 Skin Photoallergy Test		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				[Annex 2, Notice No. 136 of 2017 of the China Food and Drug Administration on the Inclusion of Two Test Methods, Including In Vitro SkinCorrosion：TranscutaneousElectricalResistance Test（TER） and Skin Photoallergy Test, into the Safety and Technical Standards for Cosmetics (2015 Edition)]		
		18	In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method	In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method OECD TG439（2021）		2026-07-28
		19	In Vitro Skin Corrosion:Reconstructed Human Epidermis (RhE) Test Method	In Vitro Skin Corrosion:Reconstructed Human Epidermis (RhE) Test Method OECD TG431（2021）		2026-07-28
		20	Short Time Exposure In Vitro Test Method (STE)	Short Time Exposure In Vitro Test Method OECD TG491 (2020)		2026-07-28
				Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 21Short Time Exposure In VitroTest Method (STE) [Annex 3, Notice No. 12 of 2019 of the National Medical Products Administration on the Inclusion of Nine Test Methods, Including the Detection Method of Free Formaldehyde in Cosmetics, into the Safety and Technical Standards for Cosmetics (2015 Edition)]		2026-07-28
		21	In Vitro Mammamlian Cells Micronucleus Test	Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 25 In Vitro Mammamlian Cells Micronucleus Test [Annex 6, Notice No. 17 of 2021 of the National Medical Products Administration on the Inclusion of Seven Test Methods,		2026-07-28

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		№	Item/ Parameter			
				Including the Test Methods for Preservatives in Cosmetics, into the Safety and Technical Standards for Cosmetics (2015 Edition)]		
		22	In Chemico Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA)	Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 24 In Chemico SkinSensitisation: DirectPeptide Reactivity [Annex 6, Notice No. 12 of 2019 of the National Medical Products Administration on the Inclusion of Nine Test Methods, Including the Detection Method of Free Formaldehyde in Cosmetics, into the Safety and Technical Standards for Cosmetics (2015 Edition)]		2026-07-28
		23	Skin Sensitization: Local Lymph Node Assay: BrdU-ELISA （LLNA:BrdU-ELISA）	Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 23 Skin Sensitization: Local Lymph Node Assay: BrdU-ELISA （LLNA:BrdU-ELISA） [Annex 5, Notice No. 12 of 2019 of the National Medical Products Administration on the Inclusion of Nine Test Methods, Including the Detection Method of Free Formaldehyde in Cosmetics, into the Safety and Technical Standards for Cosmetics (2015 Edition)]		2026-07-28
		24	In Vitro Skin Corrosion：Transcutaneous Electrical Resistance Test （TER）	Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 19In Vitro SkinCorrosion：TranscutaneousElectricalResistance Test（TER） [Annex 1, Notice No. 136 of 2017 of the China Food and Drug Administration on the Inclusion of Two Test Methods, Including In Vitro SkinCorrosion：TranscutaneousElectricalResistance Test（TER） and Skin Photoallergy Test, into the Safety and Technical Standards for Cosmetics (2015 Edition)]		2026-07-28
		25	IN VITRO SKIN SENSITISATION	IN VITRO SKIN SENSITISATION ASSAYS ADDRESSING THE AOP KEY EVENT ON KERATINOCYTE ACTIVATION		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			ASSAYS ADDRESSING THE AOP KEY EVENT ON KERATINOCYTE ACTIVATION	OECD TG442D(2022) Annex IB		
		26	Teratogenicity Test	Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 16 Teratogenicity Test [Annex 10, Notice No. 12 of 2019 of the National Medical Products Administration on the Inclusion of Nine Test Methods, Including the Detection Method of Free Formaldehyde in Cosmetics, into the Safety and Technical Standards for Cosmetics (2015 Edition)]		2026-07-28
		27	Fluorescein Leakage In Vitro Test Method	Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 28 Fluorescein Leakage In Vitro Test Method [Annex 11, Notice No. 41 of 2023 of the National Medical Products Administration on the Inclusion of Twenty One Test Methods, Including the Determination of pH in cosmetics (W/O), into the Safety and Technical Standards for Cosmetics (2015 Edition)]		2026-07-28
		28	IN VITRO SKIN SENSITISATION: HUMAN CELL LINE ACTIVATION TEST (H-CLAT)	Technical Specification for the Safety of Cosmetics (Edition 2015) Chapter 6.26 (Announcement No. 41 of 2023 by NMPA, Annex 9)		2026-07-28
		29	Skin Sensitization: Local Lymph Node Assay: DA	Technical Specification for the Safety of Cosmetics (Edition 2015) Chapter 6.22 (Announcement No. 12 of 2019 by NMPA, Annex 4)		2026-07-28

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		30	Repeated Dose 28-Day Oral Toxicity Study	Technical Specification for the Safety of Cosmetics (Edition 2015) Chapter 6.39 (Announcement No. 12 of 2024 by NMPA, Annex 8)		2026-07-28
		31	Skin Absorption: In vitro Method	Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 47 Skin Absorption: In vitro Method [Annex 4, Notice No. 32 of 2025 of the National Medical Products Administration on the Inclusion of Five Test Methods Including the Bovine Corneal Opacity and Permeability Test Method into the Safety and Technical Standards for Cosmetics (2015 Edition)]		2026-07-28
		32	Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eyeirritation or serious eye damage	Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eyeirritation or serious eye damage OECD TG 492（2025）		2026-07-28
		33	Reconstructed Human Cornea-like Epithelium (RHCE) Test Method for Eye Hazard Identification	Reconstructed Human Cornea-like Epithelium (RHCE) Test Method for Eye Hazard Identification OECD TG 492B（2024）		2026-07-28
		34	In Chemico Skin Sensitisation: Kinetic Direct	Safety and Technical Standards for Cosmetics the 2015 edition Chapter 6 Toxicology Test Methods 46In Chemico Skin Sensitisation: Kinetic Direct Peptide		2026-07-28

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		№	Item/ Parameter			
			Peptide Reactivity Assay (kDPRA)	Reactivity Assay (kDPRA) [Annex 3, Notice No. 32 of 2025 of the National Medical Products Administration on the Inclusion of Five Test Methods Including the Bovine Corneal Opacity and Permeability Test Method into the Safety and Technical Standards for Cosmetics (2015 Edition)]		

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