CERTIFICATE OF ACCREDITATION

EEThis is to attest that

EPINTEK SUZHOU LTD.

NO. 558 FENHU AVENUE, LILI TOWN, WUJIANG DISTRICT
SUZHOU, JIA, 215211, CHINA

Testing Laboratory TL-700

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories*, and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories.* This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date August 19, 2024

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Accredited to ISO/IEC 17025:2017 *Effective Date August 19, 2024*

Electrical	
AAMI ST81	Sterilization of medical device – information to be provided by the manufacturer for the processing of resterilizable medical device
AAMI ST98	Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices.
AAMI TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
AAMI TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
AAMI TIR42	Evaluation of particulates associated with vascular medical devices
ANSI/AAMI 60601-2-25	Medical electrical equipment - part 2-25: particular requirements for the basic safety and essential performance of electrocardiographs (exclusions: section 201.8.5.5.1 (defibrillation protection), section .201.17.202 (electromagnetic compatibility of ME equipment and ME systems))
ANSI/AAMI 60601-2-27	Medical electrical equipment - part 2-27: particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (exclusions: section 201.8.5.5 (defibrillation-proof applied parts), section 201.11.6.5 (IP testing), section 201.17.202 (electromagnetic compatibility of ME equipment and ME systems))
ANSI/AAMI ES60601-1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance (exclusions: section 8.5.5 (defibrillation applied parts), section 8.8.4.2 (ageing rubber in oxygen), section 8.9.1.7 (CTI test), section 9.5.2 (cathode ray tubes), section 9.6.3 (hand-transmitted vibration), section 9.7.5 (pressure vessels), section 10.3 (microwave radiation), section 11.2.2 (ME equipment and ME systems used in conjunction with oxygen rich environment), section 11.6.5 (IP test), section 15.4.2 (PTC's), section 15.4.3.4 (performance tests of primary and secondary battery), section annex a.10.4 (LEDs), section annex G (protection against hazards of ignition of flammable anesthetic mixtures))
ANSI/AAMI HA60601-1-11	Medical electrical equipment - part 1-11: collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (exclusions: section 8.3.1/8.3.2 (IP test), section

	10.1.2/10.1.3 (shock test; broad-band random vibration test; free fall test), section 12.1 (class B according to CISPR 11:2009), section 12.5 (ESD testing)
ASTM D3078	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
ASTM E1766	Determination of Effectiveness of Sterilization Processes for Reusable Medical Devices
ASTM E1837	Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)
ASTM F88/88M	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F719	Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation
ASTM F756	Standard Practice for Assessment of Hemolytic Properties of Materials
ASTM F813	Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices
ASTM F895	Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity
ASTM F1140/F1140M	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
ASTM F1886/F1886M	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F2382	Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT)
ASTM F2888	Standard Practice for Platelet Leukocyte Count—An In-Vitro Measure for Hemocompatibility Assessment of Cardiovascular Materials
ASTM F3127	Validating Cleaning Processes Used During the Manufacture of Medical Devices
ASTM F3208	Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices
ASTM F3293	Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices
CEN ISO/TS 15883-5	Washer disinfectors —Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy
CP Part IV<0903>	Insoluble Particles Test

CP Part IV <1101>	Sterility Test
CP Part IV <1105>	Microbiological Methods-Part 1：Determination of a Population of Microbial Enumeration Tests
CP Part IV <1106>	Microbiological Examination of Nonsterile Products: Control Bacteria Inspection Method
CP Part IV <1107>	Microbial Limits of Non-sterile Drugs
CP Part IV <1141>	Abnormal Toxicity Test
CP Part IV <1142>	Pyrogen Test
CP Part IV <1143>	Bacterial Endotoxins Test
CP Part IV <1147>	Allergic Test
DIN EN 13697	Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/ or fungicial activity of chemical disinfectants used in food, industrial, domestic and institutional - Test method and requirements without mechanical action (phase2, step 1)
DIN 58953-6	Sterilization - Sterile Supply - Part 6: Microbial Barrier Testing of Packaging Materials for Medical Devices Which Are to Be Sterilized
EN 285	Sterilization — Steam sterilizers — Large sterilizers
EN 455-3	Endotoxin test
EN 868-5	Packaging for terminally sterilized medical devices— Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods
EN 12184	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods
EN 13060	Small steam sterilizers
EN 13624	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase2, step 1)
EN 13697	Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/ or fungicial activity of chemical disinfectants used in food, industrial, domestic and institutional - Test method and requirements without mechanical action (phase2, step 1)
EN 13727	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase2, step 1)

EN 14885	Chemical disinfectants and antiseptics – Application of European standards for chemical disinfectants and antiseptics
EN ISO 7405	Dentistry — Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-2	Biological evaluation of medical devices – Part 2: Animal welfare requirements
EN ISO 10993-3/10993-12	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4/10993-12	Biological evaluation of medical devices – part 4: selection of tests for interactions with blood
EN ISO 10993-5/10993-12	Biological evaluation of medical devices – part 5: tests for in vitro cytotoxicity
EN ISO 10993-6/10993-12	Biological evaluation of medical devices – part 6: tests for local effects after implantation
EN ISO 10993-10/10993-12	Biological evaluation of medical devices – part 10: tests for irritation and skin sensitization
EN ISO 10993-11/10993-12	Biological evaluation of medical devices – part 11: tests for systemic toxicity
EN ISO 10993-23	Biological evaluation of medical devices — Part 23: Tests for irritation Test Methods: a. Dermal Irritation Test SOP: EPIN-SOP-AM-003 b. Intracutaneous Reactivity Test SOP: EPIN-SOP-AM-004 c. Ocular Irritation Test SOP: EPIN-SOP-AM-005 d. Vaginal Irritation Test SOP: EPIN-SOP-AM-006 e. Oral Mucosa Irritation Test SOP: EPIN-SOP-AM-007 f. Penis Irritation Test SOP: EPIN-SOP-AM-008 g. Rectal Irritation Test SOP: EPIN-SOP-AM-009
EN ISO 11607-1	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11737-1	Sterilization of health care products —Microbiological methods — Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2	Sterilization of health care products—Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

EN ISO 15883-1	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests
EN ISO 15883-2	Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
EN ISO 17664-1	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices
EN ISO 17665	Sterilization of health care products - Moist heat Requirements for the development, validation and routine control of a sterilization process for medical devices
EN/ISO 80601-2-61	Medical electrical equipment – part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment (exclusions: section 201.10 (protection against unwanted and excessive radiation hazards – test per IEC 62471:2006 and IEC 60825-2:2004+A1:2006), section 201.11.6.5 (ingress of water or particulate matter into ME equipment and ME systems), section 201.15.3.5.101 (additional requirements for rough handling), section 201.17 (electromagnetic compatibility of ME equipment and ME systems) section 202 (electromagnetic compatibility- requirements and tests))
GB 18278.1	Sterilization of health care products - Moist heat Requirements for the development, validation and routine control of a sterilization process for medical devices
GB/T 14233.2	Test methods for infusion, transfusion, injection equipment for medical use— Part 2: Biological test methods
GB/T 16293	Test method for airborne microbe in clean room(zone) of the pharmaceutical industry
GB/T 16886.1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
GB/T 16886.2	Biological evaluation of medical devices – Part 2: Animal welfare requirements
GB/T 16886.3/16886.12	Biological evaluation of medical devices – part 3: tests for genotoxicity, carcinogenicity and reproductive toxicity
GB/T 16886.4/16886.12	Biological evaluation of medical devices – part 4: selection of tests for interactions with blood
GB/T 16886.5/16886.12	Biological evaluation of medical devices – part 5: tests for in vitro cytotoxicity
GB/T 16886.6/16886.12	Biological evaluation of medical devices – part 6: tests for local effects after implantation
GB/T 16886.10/16886.12	Biological evaluation of medical devices – part 10: tests for irritation and skin sensitization

GB/T 16886.11/16886.12	Biological evaluation of medical devices – part 11: tests for systemic toxicity
GB/T 16886.23	Biological evaluation of medical devices — Part 23: Tests for irritation Test Methods: a. Dermal Irritation Test SOP: EPIN-SOP-AM-003 b. Intracutaneous Reactivity Test SOP: EPIN-SOP-AM-004 c. Ocular Irritation Test SOP: EPIN-SOP-AM-005 d. Vaginal Irritation Test SOP: EPIN-SOP-AM-006 e. Oral Mucosa Irritation Test SOP: EPIN-SOP-AM-007 f. Penis Irritation Test SOP: EPIN-SOP-AM-008 g. Rectal Irritation Test SOP: EPIN-SOP-AM-009
GB/T 19973.1	Sterilization of medical devices —Microbiological methods — Part 1: Determination of a population of microorganisms on products
GB/T 19973.2	Sterilization of medical devices —Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process
IEC/EN 60204-1	Safety of machinery —electrical equipment of machines —part 1: general requirements (exclusions: section 18.2.2 (test methods in TN-systems - test 2 – fault loop impedance test)
IEC/EN 60601-1	Medical electrical equipment - part 1: general requirements for basic safety and essential performance (exclusions: section 8.5.5 (defibrillation applied parts), section 8.8.4.2 (ageing rubber in oxygen), section 8.9.1.7 (CTI Test), section 9.5.2 (cathode ray tubes), section 9.6.3 (hand-transmitted vibration), section 9.7.5 (pressure vessels), section 10.3 (microwave radiation), section 11.2.2 (ME equipment and ME systems used in conjunction with oxygen rich environment), section 11.6.5 (IP test), section 15.4.2 (PTC's), section 15.4.3.4 (performance tests of primary and secondary battery), section annex A.10.4 (LEDs), section annex G (protection against hazards of ignition of flammable anesthetic mixtures))
IEC/EN 60601-1(EQV)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC/EN 60601-1-6	Medical electrical equipment - part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC/EN 60601-1-8	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/EN 60601-1-11	Medical electrical equipment - part 1-11: collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (exclusions: section 8.3.1/8.3.2 (IP test), section 10.1.2/10.1.3 (shock test; broad-band random vibration test; free fall test), section 12.1 (class B according to CISPR 11:2009), section 12.5 (ESD testing))
IEC/EN 60601-2-2	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
IEC/EN 60601-2-10	Medical electrical equipment - part 2-10: particular requirements for the basic safety and essential performance of nerve and muscle stimulators (exclusions: section 201.17 (electromagnetic compatibility of ME equipment and ME systems), section 202 (electromagnetic compatibility – requirements and tests))
IEC/EN 60601-2-18	Medical electrical equipment – part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment (exclusions: section 201.11.6.5 (ingress of water or particulate matter into ME equipment and ME systems), section 201.17 (electromagnetic compatibility of ME equipment and ME systems), section 202 (electromagnetic compatibility – requirements and tests)
IEC/EN 60601-2-19	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
IEC/EN 60601-2-20	Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
IEC/EN 60601-2-21	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
IEC/EN 60601-2-22	Medical electrical equipment - part 2-22: particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC/EN 60601-2-24	Medical electrical equipment - part 2-24: particular requirements for the basic safety and essential performance of infusion pumps and controllers (exclusions: section 201.11.6.3/201.11.6.5 (IP testing), section 201.12.1 (accuracy of controls and instruments), section 201.12.4.4.104 (protection against unintended BOLUS volumes and by occlusion), section 201.17.202 (electromagnetic compatibility of ME equipment and ME systems))
IEC 60601-2-25	Medical electrical equipment - part 2-25: particular requirements for the basic safety and essential performance of electrocardiographs (exclusions: section 201.8.5.5.1 (defibrillation protection), section .201.17.202 (electromagnetic compatibility of ME equipment and ME systems))
IEC/EN 60601-2-27	Medical electrical equipment - part 2-27: particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (exclusions: section 201.8.5.5 (defibrillation-proof applied parts), section 201.11.6.5 (IP testing), section 201.17.202 (electromagnetic compatibility of me equipment and me systems))

IEC/EN 80601-2-30	Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (exclusions: section 201.11.6.5 (ingress of water or particulate matter into ME equipment and ME systems), section 201.15.2.5.102 (shock and vibration for other than transport), section 201.15.2.5.102 (shock and vibration for transport), section 201.17 (electromagnetic compatibility of ME equipment and ME systems), section 202 (electromagnetic compatibility- requirements and tests))
IEC/EN 60601-2-41	Medical electrical equipment - part 2-41: particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis (exclusions: section 201.17 (electromagnetic compatibility of ME equipment and ME systems))
IEC/EN 60601-2-46	Medical electrical equipment - part 2-46: particular requirements for the basic safety and essential performance of operating tables (exclusions: section 201.11.6.5 (ingress of water or particulate matter into ME equipment and ME systems), section 201.17 (electromagnetic compatibility of ME equipment and ME systems) section 202 ((electromagnetic compatibility- requirements and tests))
IEC/EN 60601-2-50	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment
IEC/EN 60601-2-52	Medical electrical equipment –part 2-52: particular requirements for basic safety and essential performance of medical beds (exclusions: section 201.11.6.5 (ingress of water or particulate matter into ME equipment and ME systems), section 201.17 (electromagnetic compatibility of ME equipment and ME systems) section 202 ((electromagnetic compatibility- requirements and tests))
IEC/EN 60601-2-57	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 (exclusions: tests per IEC 62471)
IEC/EN 60825-1	Safety of laser products - part 1: equipment classification and requirements
IEC/EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – part 1: general requirements (exclusions: section 6.7.1.3 (CTI test), section 9.3.1/14.7 (flammability test), section 10.5.3 (vicat test), section 11.6 (IP testing), section 11.7 (fluid pressure & leakage), section 12.3 (UV radiation), section 12.4 (microwave radiation), section 12.5.2 (ultrasonic pressure), section 13.2.3 (high vacuum devices))
IEC/EN 61010-2-010	Safety requirements for electrical equipment for measurement, control and laboratory use – part 2-010: particular requirements for laboratory equipment for the heating of materials
IEC/EN 61010-2-040	Safety requirements for electrical equipment for measurement, control and laboratory use – part 2-040: particular requirements for sterilizers and washer-disinfectors used to treat medical materials

IEC/EN 61010-2-081	Safety requirements for electrical equipment for measurement, control and laboratory use – part 2-081: particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC/EN 61010-2-101	Safety requirements for electrical equipment for measurement, control, and laboratory use – part 2-101: particular requirements for in vitro diagnostic (IVD)
IEC/EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
IEC/EN 62368-1	Audio/video, information and communication technology equipment – part 1: safety requirements (exclusions: section 5.4.1.11 (vicat test), section 5.4.2, 5.4.3, 5.4.4 (impulse test generator circuit 1 and circuit 3 of table D.1), section 5.4.5.1 (antenna terminal insulation), section 5.4.7 (thermal cycling test), section .8.5.5.2.2 (high pressure lamps), section 8.6.3.1(glass slide test), section 8.12 (telescoping or rod antennas), section 10 (radiations), section annex E (test conditions for equipment contain audit amplifiers), section annex G.9 (power supply cord tests), section annex G.13 (IC current limiters), section annex G.14 (test for resistor serving as safeguard), section annex G.18.6. (abrasion resistance test), section annex G.21 (liquid filled components), section annex M.6.1.2 (test to simulate internal faults nail piercing test), section annex M.8 (spark test), section annex S (tests for resistance to heat and fire), section annex U (mechanical strength of CRTs and protection against the effects of implosion))
IEC/EN 80601-2-60	Medical electrical equipment – part 2-60: particular requirements for the basic safety and essential performance of dental equipment (exclusions: section 201.8.10.4.101 (HF surgical equipment that is incorporated in the dental equipment), section 201.10.4 (LEDs), section 201.17 (electromagnetic compatibility of ME equipment and ME systems))
ISO 7405	Dentistry — Evaluation of biocompatibility of medical devices
ISO 7494-1	Dentistry -- Dental units -- Part 1: General requirements and test methods
ISO 7494-2	Dentistry -- Dental units -- Part 2: Air, water, suction and wastewater systems
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-2	Biological evaluation of medical devices – Part 2: Animal welfare requirements
ISO 10993-3/10993-12	Biological evaluation of medical devices – part 3: tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4/10993-12	Biological evaluation of medical devices – part 4: selection of tests for interactions with blood
ISO 10993-5/10993-12	Biological evaluation of medical devices – part 5: tests for in vitro cytotoxicity
ISO 10993-6/10993-12	Biological evaluation of medical devices – part 6: tests for local effects after implantation

ISO 10993-10/10993-12	Biological evaluation of medical devices – part 10: tests for irritation and skin sensitization
ISO 10993-11/10993-12	Biological evaluation of medical devices – part 11: tests for systemic toxicity
ISO 10993-12	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 10993-23	Biological evaluation of medical devices — Part 23: Tests for irritation Test Methods: h. Dermal Irritation Test SOP: EPIN-SOP-AM-003 i. Intracutaneous Reactivity Test SOP: EPIN-SOP-AM-004 j. Ocular Irritation Test SOP: EPIN-SOP-AM-005 k. Vaginal Irritation Test SOP: EPIN-SOP-AM-006 l. Oral Mucosa Irritation Test SOP: EPIN-SOP-AM-007 m. Penis Irritation Test SOP: EPIN-SOP-AM-008 n. Rectal Irritation Test SOP: EPIN-SOP-AM-009
ISO 11607-1	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier
ISO 11737-1	Sterilization of medical devices —microbiological methods — part 1: determination of a population of microorganisms on products
ISO 11737-2	Sterilization of medical devices – microbiological methods – part 2: tests of sterility-performed in the definition, validation and maintenance of a sterilization process
ISO 15883-1	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests
ISO 15883-2	Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
ISO 17664-1	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices
ISO 17664-2	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2: Non-Critical medical devices

ISO 17665	Sterilization of health care products - Moist heat Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO /TR 10993-33	Biological evaluation of medical devices – part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3
ISO/TS 15883-5	Washer disinfectors —Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy
OECD 452	Chronic Toxicity Studies
OECD 471	Bacterial Reverse Mutation Test
OECD 473	In vitro Mammalian Chromosomal Aberration Test
OECD 474	Mammalian Erythrocyte Micronucleus Test
OECD 476	In Vitro Mammalian Cell Gene Mutation Tests using the Hprt and xprt genes
OECD 490	In Vitro Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene
Ph. Eur. Method 2.6.1	Test for Sterility
Ph. Eur. Method 2.6.8	Test for Pyrogens
Ph. Eur. Method 2.6.14	Test for Bacterial Endotoxins (LAL Test)
T/CAMDI 009	Sterile Medical Device Package - Part 1： Test methods for particulate matter
UL 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – part 1: general requirements (exclusions: section DVD.4 (conduit enclosure entry tests))
USP <51>	Antimicrobial effectiveness testing
USP <61>	Microbiological Examination of Nonsterile Products: Microbial enumeration tests
USP <71>	Sterility tests
USP <85>	Bacterial Endotoxin tests
USP <87>	Biological Reactivity Tests, in vitro
USP <88>	Biological Reactivity Tests, in vivo
USP<151>	Pyrogen Test
USP <788>	Particulate Matter in Injections. Method 1: Light obscuration particle count test.
USP <1113>	Microbial Characterization, Identification, and Strain Typing
USP <1184>	Sensitization Testing

WS 310.1	Central sterile supply department (CSSD)-Part 1: Management standard
WS 310.2	Central sterile supply department (CSSD)-Part 2: Standard for oprating procedure of cleaning, disinfection and sterilization
WS 310.3	Central sterile supply department (CSSD)-Part 3: Surveillance standard for cleaning, disinfection and sterilization
WS/T 367	Regulation of disinfection technique in healthcare settings
YBB 00012003	Test for Cytotoxicity
YBB 00272004	Test for Insoluble Particulate Matter of Packing Materials
YY 0719.7	Ophthalmic optics–Contact lens care products–Part 7: Biological evaluation test methods
YY/T 0127.1	Biological evaluation of medical devices used in dentistry– Part 2: Tests method–hemolytic
YY/T 0127.4	Biological evaluation of medical devices used in dentistry– Part 2: Tests method–Bone implant test
YY/T 0127.8	Biological evaluation of dental material – Part 2: Biological evaluation test method of dental materials–Subcutaneous implant test
YY/T 0127.9	Biological evaluation of medical devices used in dentistry– Part 2: Tests method–Cytotoxicity tests: Agar diffusion test and filter diffusion test
YY/T 0127.12	Dentistry— Biological evaluation of medical devices used in dentistry– Part 2: tests method–Micronucleus test
YY/T 0127.13	Biological evaluation of medical devices used in dentistry– Part 13: Oral mucous irritation test
YY/T 0127.14	Biological evaluation of medical devices used in dentistry– Part 2: Tests method–Acute oral toxicity test
YY/T 0127.15	Biological evaluation of medical devices used in dentistry– Part 15: Subactute and aubchronic systemic toxicity test: oral route
YY/T 0127.16	Biological evaluation of medical devices used in dentistry– Part 2: Test method–In vitro mammalian chromosome aberration test
YY/T 0127.17	Biological evaluation of medical devices used in dentistry– Part 17: Mouse lymphoma cells （TK） gene mutation test
YY/T 0268	Dentistry—Biological evaluation of medical devices used in dentistry—Part 1：Evaluation and test
YY/T 0802	Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices

YY/T 0870.2	Tests for genotoxicity of medical devices—Part 2: In vitro mammalian chromosome aberration test
YY/T 0870.3	Tests for genotoxicity of medical devices—Part 3: In vitro mammalian cell gene mutation test using mouse lymphoma cells
YY/T 0870.4	Tests for genotoxicity of medical devices—Part 4: Mammalian bone marrow erythocyte micronucleus test
YY/T 0878.3	Test for complement activation of medical devices —Parts 3：Assay for the product of complement activation（C3a and SC5b-9）
YY/T 1495	Microbiological test method for demonstrating cleaning and disinfection efficacy
YY/T 1623	Test method of effectiveness of sterilization processes for reusable medical devices

AAMI: Association for the Advancement of Medical Instrumentation

IEC: International Electrotechnical Commission

UL: Underwriters Laboratories

USP: United States Pharmacopeia