CERTIFICATE OF ACCREDITATION

This is to attest that

CCIC HUATONGWEI INTERNATIONAL INSPECTION (SUZHOU) CO., LTD

NO.107, CHANGYANG ROAD, INDUSTRIAL PARK
SUZHOU, 215000, CHINA

Testing Laboratory TL-1237

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 May 29, 2024

IAS ACCREDITED

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SCOPE OF ACCREDITATION

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CCIC HUATONGWEI INTERNATIONAL INSPECTION (SUZHOU) CO., LTD

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Accredited to ISO/IEC 17025:2017 *Effective Date May 29, 2024*

Medical Device Testing	
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)] (Exclusions: 9.5.2 Cathode ray tubes 9.6.2.2 Infrasound and Ultrasound Energy 9.6.3 Hand-transmitted vibration 10.1.1 ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation 10.3 Microwave Radiation 10.4 Lasers 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 12.4.5.2 Diagnostic X-ray equipment)
ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021]	Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)]
ANSI/AAMI/IEC 60601-1-2:2014	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
ANSI AAMI ISO 11737-2:2019(2014)	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition validation and maintenance of a sterilization process
ASTM D3078-02 (Reapproved 2021)e1	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
ASTM D4169-23	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM E1112-00(2018)	Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
ASTM E1965-98 (Reapproved 2023)	Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

ASTM F88/F88M-23	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F619-20 2020-09-18	Standard Practice for Extraction of Materials Used in Medical Devices
ASTM F756-17	Standard Practice for Assessment of Hemolytic Properties of Materials
ASTM F1140-2013(2020)e1	Standard Test Methods For Internal Pressurization Failure Resistance Of Unrestrained Packages
ASTM F1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929-23	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1984-99 2018-02-01	Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials
ASTM F2096-11 (Reapproved 2019)	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F2382-18 2018-10-01	Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT)
ASTM F2888-19 2019-02-01	Standard Practice for Platelet Leukocyte Count—An In-Vitro Measure for Hemocompatibility Assessment of Cardiovascular Materials
DIN 58953-6:2023	Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized.
EN 14683：2019+AC：2019	Medical face masks - Requirements and test methods
EN 60601-1:2006+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-6:2010+A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2007+A2:2021	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
EN 60601-2-10:2015+A1:2016	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
EN 60601-1-11:2015+A1:2021	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 60601-1-12:2015+A1:2020	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 environment
EN 60601-2-18:2015	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
EN 60601-2-24:2015	Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
EN 60601-2-25:2015	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN 60601-2-27:2014	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
EN 60601-2-47:2015	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
EN 60601-2-52: 2010+A1:2015	Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
EN 61010-1:2010+A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN IEC 60601-2-2:2018	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
EN IEC 60601-2-39:2019	Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
EN IEC 60601-2-46:2019	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

EN IEC 61010-2-010:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN IEC 61010-2-030:2021+A11:2021	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-030: Particular requirements for equipment having testing or measuring circuits (Exclusions: 12.2 Ionization Radiation 12.3 Optical radiation only measurement 12.4 Microwave radiation 12.6 Laser Sources 13.2.3 Implosion of cathode ray tubes)
EN IEC 61010-2-040:2021	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
EN IEC 61010-2-051:2021+A11:2021	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring
EN IEC 61010-2-081:2020	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
EN IEC 61010-2-101:2022+A11:2022	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN IEC 80601-2-30:2019	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
EN IEC 80601-2-49:2019	Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)

EN IEC 80601-2-60:2020	Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
EN ISO 10993-3:2014	Biological evaluation of medical device - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
EN ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
EN ISO 80601-2-56:2017+A1:2020	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
EN ISO 80601-2-61:2019	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
EN ISO 80601-2-69:2020	Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
EN ISO 81060-1:2012	Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type
IEC 60601-1 Edition 3.2 2020-08	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied see references #1 and #2 in the Relevant FDA

CONSOLIDATED VERSION	Guidance and/or Supportive Publication section below. (Exclusions: 9.5.2 Cathode ray tubes 9.6.2.2 Infrasound and Ultrasound Energy 9.6.3 Hand-transmitted vibration 10.1.1 ME Equipment not intended to produce diagnostic or therapeutic X-radiation 10.3 Microwave Radiation 10.4 Lasers 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 12.4.5.2 Diagnostic X-ray equipment)
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	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 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	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 environment
IEC 60601-2-2 Edition 6.0 2017-03 [Including AMD1:2023]	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 (Exclusions: 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201.9.6.3 Hand-transmitted vibration 201.10.1.1 ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation 201.10.3 Microwave Radiation 201.10.4 Lasers

	201.11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201.11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201.12.4.5.2 Diagnostic X-ray equipment 201.15.101.5 NE thermal performance Sub Clauses apply to general standard except 201.15.101.5)
IEC 60601-2-4 Edition 3.1 2018-02 CONSOLIDATED VERSION	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation 201.15.101.5 NE thermal performance Sub Clauses apply to general standard except 201.15.101.5)
IEC 60601-2-10 Edition 2.1 2016-04[Including AMD2:2023]	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (Exclusions: 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201.9.6.3 Hand-transmitted vibration 201.10.1.1 ME Equipment not intended to produce diagnostic or therapeutic X-radiation 201.10.3 Microwave Radiation 201.10.4 Lasers 201.11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201.11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201.12.4.5.2 Diagnostic X-ray equipment Sub Clauses apply to general standard)
IEC 60601-2-18: Edition 3.0 2009-08	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-25 Edition 2.0 2011-10	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-27 Edition 3.0 2011-03	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment [Including: Corrigendum 1 (2012)]
IEC 60601-2-34 Edition 3.0 2011-05	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety including essential performance of invasive blood pressure monitoring equipment (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration

	201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
IEC 60601-2-35 Edition 2.0 2020-09	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets pads and mattresses and intended for heating in medical use (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
IEC 60601-2-37 Edition 2.1 2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-39 Edition 3.0 2018-04	Medical electrical equipment Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment
IEC 60601-2-47 Edition 2.0 2012-02	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
IEC 60601-2-52 Edition 1.1 2015-03 CONSOLIDATED VERSION	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds [Including: Technical Corrigendum 1 (2010)]
IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION	Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)] - Note: This standard is recognized with relevant US national differences applied see reference #1 in Relevant FDA Guidance and/or Supportive Publication section
IEC 61010-2-010:2019	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 61010-2-030:2023	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-030: Particular requirements for equipment having testing or measuring circuits (Exclusions: 12.2 Ionization Radiation 12.3 Optical radiation only measurement 12.4 Microwave radiation 12.6 Laser Sources 13.2.3 Implosion of cathode ray tubes)

IEC 61010-2-040:2020	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 61010-2-051:2018	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring
IEC 61010-2-081:2019	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 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61326-1 Edition 3.0 2020-10	Electrical equipment for measurement control and laboratory use - EMC requirements - Part 1: General requirements
IEC 80601-2-30: Edition 2.0 2018-03	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
IEC 80601-2-60 Edition 2.0 2019-06	Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
IEC TS 60601-4-2:2024	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
ISO 7405:2018-10 6.2 6.3	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-2 Third edition 2022-11-03	Biological Evaluation of medical devices - Part 2: Animal welfare requirements
ISO 10993-3 Third edition 2014-10-1	Biological evaluation of medical devices - Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity
ISO 10993-4 Third edition 2017-04	Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-6 Third edition 2016-12-01	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
ISO 10993-9 Third edition 2019-11	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
ISO 10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-11 Third edition 2017-09	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-12 Fifth edition 2021-01	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
ISO 10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation
ISO 11607-1 Second edition 2019-01[Including AMD1:2023]	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems
ISO 11607-2 Second edition 2019-01[Including AMD1:2023]	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes
ISO 11737-1 Third edition 2018-01 [Including AMD1:2021]	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including Amendment 1 (2021)]
ISO 11737-2 Third edition 2019-12	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition validation and maintenance of a sterilization process
ISO 15004-1 Second edition 2020-5	Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments
ISO 17664 First edition 2021-07	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 17664-1 First edition 2021-07	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 First edition 2021-02	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 20857 First edition 2010-08-17	Sterilization of health care products - Dry heat - Requirements for the development validation and routine control of a sterilization process for medical devices
ISO 80601-2-56 Second edition 2017-03	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)]. (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy

	201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
ISO 80601-2-61 Second edition 2017-12(Corrected version 2018-02)	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
ISO 80601-2-69 Second edition 2020-11	Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment (Exclusions: 201. 9.5.2 Cathode ray tubes 201. 9.6.2.2 Infrasound and Ultrasound Energy 201. 9.6.3 Hand-transmitted vibration 201. 10 Protection against unwanted and excessive radiation hazards 201. 11.2.2 ME Equipment and ME Systems used in conjunction with oxygen rich environments 201. 11.2.3 single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems 201. 12.4.5 Diagnostic or therapeutic radiation Sub Clauses apply to general standard)
ISO 81060-1 First edition 2007-12-01	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type
ISO/TR 10993-33 First Edition 2015-03-01	Biological evaluation of medical devices - Part 33: Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3
ISO/TS 10993-19 Second edition 2020-03	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials
ISO/TS 10993-20 First edition 2006-08-01	Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices
OECD TG 471, 2020	Bacterial Reverse Mutation Test
OECD TG 473, 2016	In Vitro Mammalian Chromosomal Aberration Test
OECD TG 474 2016	Mammalian Erythrocyte Micronucleus Test
OECD TG 490, 2016	In Vitro Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene
US Pharmacopoeia,43	<51>Antimicrobial Effectiveness Testing

USP-NF M98800-01-01	<61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests
USP-NF M98802-01-01	<62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms
USP-NF M98810-01-01	<71> Sterility Tests
USP-NF M98830-02-01	<85>Bacterial Endotoxins Test
USP-NF M98833-01-01	<87> Biological Reactivity Test In Vitro - Direct Contact Test
USP-NF M98833-01-01	<87> Biological Reactivity Test In Vitro - Elution Test
USP-NF M98834-01-01	<88> Biological Reactivity Tests In Vivo
USP-NF M98900-01-01	<151> Pyrogen Test (USP Rabbit Test)