CERTIFICATE OF ACCREDITATION

This is to attest that

SHANGHAI SUNGO MEDICAL TECHNOLOGY CO. LTD.

ROOM 218, BUILDING B, NO. 958, KANGQIAO EAST ROAD, KANGQIAO INDUSTRIAL ZONE, PUDONG DISTRICT, SHANGHAI 201315, PEOPLE'S REPUBLIC OF CHINA

Testing Laboratory TL-1019

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 December 20, 2023

IAS ACCREDITED

President

Visit www.iasonline.org for current accreditation information.

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

SHANGHAI SUNGO MEDICAL TECHNOLOGY CO. LTD.

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Accredited to ISO/IEC 17025:2017 *Effective Date December 20, 2023*

AAMI ST98	Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices Only accredited for manual cleaning validation
AAMI TIR12	Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers Only accredited for manual cleaning validation, manual disinfection (disinfectant), half cycle sterilization method
AAMI TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices Only accredited for manual cleaning validation
AATCC TM 42	Water Resistance: Impact Penetration Test
AATCC TM 127	Test Method for Water Resistance: Hydrostatic Pressure
ANSI/AAMI PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities
ASTM D1683/D1683M	Standard Test Method for Failure in Sewn Seams of Woven Fabrics
ASTM D3078	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
ASTM D3578	Standard Specification for Rubber Examination Gloves
ASTM D3776/D3776M	Standard Test Methods for Mass Per Unit Area (Weight) of Fabric
ASTM D5034	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
ASTM D5151	Standard Test Method for Detection of Holes in Medical Gloves
ASTM D5250	Standard Specification for Poly (vinyl chloride) Gloves for Medical Application
ASTM D5587	Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
ASTM D6124	Standard Test Method for Residual Powder on Medical Gloves
ASTM D6319	Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM D6977	Standard Specification for Polychloroprene Examination Gloves for Medical Application
ASTM F88/F88M	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1140/F1140M	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages - Test Method A

ASTM F1608	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
ASTM F1670/F1670M	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
ASTM F1671/F1671M	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System
ASTM F1862/F1862M	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
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 F2100	Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F2101	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
ASTM F2407	Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities
BS EN 455-1	Medical gloves for single use – Part 1: Requirements and testing for freedom from holes
BS EN 455-2	Medical gloves for single use – Part 2: Requirements and testing for physical properties
BS EN 455-3	Medical gloves for single use – Part 3: Requirements and testing for biological evaluation only 5.2
BS EN 455-4	Medical gloves for single use – Part 4: Requirements and testing for shelf life determination
BS EN 14683	Medical face masks – Requirements and test methods
BS EN ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
DIN 58953-6	Sterilization - Sterile Supply - Part 6: Microbial Barrier Testing of Packaging Materials for Medical Devices Which Are to Be Sterilized
EN 455-1	Medical gloves for single use – Part 1: Requirements and testing for freedom from holes
EN 455-2	Medical gloves for single use – Part 2: Requirements and testing for physical properties
EN 455-3	Medical gloves for single use – Part 3: Requirements and testing for biological evaluation only 5.2

EN 455-4	Medical gloves for single use – Part 4: Requirements and testing for shelf life determination
EN 13726-1	Test methods for primary wound dressings - Part 1: Aspects of absorbency
EN 13726-4	Non-active medical devices - Test methods for primary wound dressings - Part 4: Conformability
EN 13795-1	Surgical clothing and drapes – Requirements and test methods – Part 1: Surgical drapes and gowns
EN 13795-2	Surgical clothing and drapes – Requirements and test methods – Part 2: Clean air suits
EN 13795-3	Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment – Part 3: Performance requirements and performance levels
EN 14079	Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze
EN 14683	Medical face masks – Requirements and test methods
EN 29073-3	Textiles – Test Methods for Nonwovens – Part 3: Determination of Tensile Strength and Elongation
EN ISO 21171	Medical gloves Determination of removable surface powder
GB 10213	Single-use medical rubber examination gloves
GB 15979	Hygienic standard for disposable sanitary products – Annex B: Determination of a population of microorganisms on products
GB 18278.1	Sterilization of health care products- Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
GB 24786	Single-use medical poly (vinyl chloride) examination gloves
GB 24787	Single-use non-sterile rubber surgical gloves
GB 50333	Architectural technical code for hospital clean operating department Accredited only for Annex 13.3
GB 50591	Code for construction and acceptance of cleanroom Accredited only for Annex E.5, E.1, E.2, E.7
GB/T 458	Paper and board - Determination of air permeance
GB/T 14233.1	Test methods for infusion, transfusion, injection equipment for medical use Part 1: Chemical analysis methods-9: EO residue-GC
GB/T 14233.2	Test methods for infusion, transfusion, injection equipment for medical use. Part 2: Biological test methods-3: Sterility test
GB/T 15171	Test method for leaks in sealed flexible packages
GB/T 16292	Test method for airborne particles in clean room (zone) of the pharmaceutical industry
GB/T 16293	Test method for airborne microbe in clean room (zone) of the pharmaceutical industry

GB/T 16294	Test method for setting microbe in clean room (zone) of the pharmaceutical industry
GB/T 16886.7	Biological evaluation of medical devices Part 7: ethylene oxide sterilization residue- Annex B: Gas chromatographic determination for EO and ECH
GB/T 18280.2	Sterilization of health care products. Radiation- Part 2: Establishing the sterilization dose Only accredited for Radiation sterilization dose setting (VDmax15or25), Radiation sterilization dose setting (VDmax15or25), Sterilization Dose Review (Method 1), Sterilization dose review (VDmax15or25)
GB/T 19633.1	Packaging of terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems
GB/T 21869	Medical gloves - Determination of removable surface powder
GB/T 34986	Methods for product accelerated testing Only accredited for B type quantitative accelerated tests for temperature, humidity and their combinations
IEC 62506	Methods for product accelerated testing Only accredited for B type quantitative accelerated tests for temperature, humidity and their combinations
ISO 5636-5	Paper and board - Determination of air permeance (medium range) - Part 5: Gurley method
ISO 10993-7	Biological evaluation of medical devices Part 7: ethylene oxide sterilization residue- Annex B: Gas chromatographic determination for EO and ECH
ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose Only accredited for: Radiation sterilization dose setting (VDmax15or25), Radiation sterilization dose setting (VDmax15or25), Sterilization Dose Review (Method 1), Sterilization dose review (VDmax15or25)
ISO 11193-1	Single-use medical rubber examination gloves - Part 1: Specification for gloves made from rubber latex or rubber solution
ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11737-1	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
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 (Third edition)
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 Only accredited for manual cleaning validation, manual disinfection (disinfectant), half cycle sterilization method
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

	Only accredited for manual cleaning validation, manual disinfection (disinfectant), half cycle sterilization method
ISO 17665-1	Sterilization of health care products Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 22609	Clothing for protection against infectious agents – Medical face masks – Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
Pharmacopoeia version 2020	Pharmacopoeia issued by National Pharmacopoeia Commission of China, Volume 4, Section 1011 Sterile test method Only accredited for medical device testing
Technical Standard For disinfection	Technical Standard for Disinfection issued by Ministry of Health of China (2002) Accredited only for 2.1.7.5.2 Microbial barrier test for breathable materials
US 16 CFR Part 1610	Standard for Flammability of Clothing Textiles
YY 0033	Good manufacture practice for sterile medical devices Accredited only for Annex C
YY 0331	Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze
YY 0469	Surgical mask Except for 5.6.2, 5.11, 5.12, 5.13
YY 0471.1	Test methods for primary wound dressing - Part 1: Aspects of absorbency
YY 0471.4	Test methods for primary wound dressing - Part 4: Conformability
YY/T 0506.2	Surgical drapes, gowns and clean air suits for patients, clinical staff and equipment. Part 2: Performance requirements and test methods Accredited only for A2, A5, A6, A7
YY/T 0681.1	Test methods for sterile medical device package. Part 1: Test guide for accelerated aging
YY/T 0681.2	Test methods for sterile medical device package. Part 2: Seal strength of flexible battier materials
YY/T 0681.3	Test methods for sterile medical device package - Part 3: Internal pressurization failure resistance of unrestrained packages
YY/T 0681.4	Test methods for sterile medical device package. Part 4: Detecting seal leaks in porous packages by dye penetration
YY/T 0681.10	Test methods for sterile medical device package--Part 10: Test for microbial barrier ranking of porous package material
YY/T 0681.11	Test methods for sterile medical device package - Part 11: Determining integrity of seals for medical packaging by visual inspection
YY/T 0681.14	Test methods for sterile medical device package. Part 14: Testing the microbial barrier for porous packaging materials under moist conditions and with passage of air

YY/T 0802	Processing of medical devices - Information to be provided by the medical device manufacturer Only accredited for manual cleaning validation, manual disinfection (disinfectant), half cycle sterilization method
YY/T 0969	Single-use medical face mask Except for 5.9