CERTIFICATE OF ACCREDITATION

This is to attest that

EPINTEK GUIYANG LTD.

INDUSTRIAL INCUBATION PARK, DAYANG ROAD, BAIYUN DISTRICT
GUIYANG, 550014, CHINA

Testing Laboratory TL-1141

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 24, 2024

President

Visit www.iasonline.org for current accreditation information.

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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EPINTEK GUIYANG LTD.

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Accredited to ISO/IEC 17025:2017 *Effective Date May 24, 2024*

Biological	
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
ASTM E1766	Determination of Effectiveness of Sterilization Processes for Reusable Medical Devices
ASTM E1837	Standard Test Method for Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)
ASTM E2314	Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)
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
ASTM F3438	Standard Guide for Detection and Quantification of Cleaning Markers (Analytes) for the Validation of Cleaning Methods for Reusable Medical Devices
EN 455-3	Medical gloves for single use. Part 3: Requirements and testing for biological evaluation Section 4.3: Endotoxins
EN ISO 7405	Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry Section 5.4.3: In vitro cytotoxicity test
EN ISO 10993-5	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-6	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation Annex A: Test methods for implantation in subcutaneous tissue Annex B: Test method for implantation in muscle
EN ISO 10993-10	Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity Section 5: Acute systemic toxicity Section 6: Repeated exposure systemic toxicity (subacute, subchronic and chronic systemic toxicity)
EN ISO 10993-23	Biological evaluation of medical devices — Part 23: Tests for irritation Section 7: In vivo irritation tests Section 8: Human skin irritation test
GB 27955	Hygienic requirements for low-temperature hydrogen peroxide gas plasma sterilizer
ISO 7405	Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry Section 5.4.3: In vitro cytotoxicity test
ISO 8536-4	Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed Section 9: Biological requirements
ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process Section 6.3: Biological testing
ISO 10993-2	Biological evaluation of medical devices — Part 2: Animal welfare requirements
ISO 10993-3	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity Section 5: Genotoxicity tests
ISO 10993-4	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
ISO 10993-5	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-6	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation Annex A: Test methods for implantation in subcutaneous tissue Annex B: Test method for implantation in muscle
ISO 10993-10	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
ISO 10993-11	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity Section 5: Acute systemic toxicity Section 6: Repeated exposure systemic toxicity (subacute, subchronic and chronic 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 Section 7: In vivo irritation tests Section 8: Human skin irritation test
ISO 11135/ GB 18279.1/GB 18279	Sterilization of health care products — Ethylene oxide — Part 1：Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11138-2	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 11737-1/ EN ISO 11737-1/ GB/T 19973.1	Sterilization of health care products —Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 11737-2/ EN ISO 11737-2/ GB/T 19973.2	Sterilization of health care products—Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 14937/ EN ISO 14937/ GB/T 19974	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 17664-1/ 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
ISO 17664-2/ EN 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/ EN ISO 17665-1/ 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
ISO 18562-4	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate Section 5.2 d~e
ISO /TR 10993-33	Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3– Supplement to ISO 10993-3 Section 6: Bacterial reverse mutation assay
USP <87>	Biological Reactivity Tests, in vitro
USP <88>	Biological Reactivity Tests, in vivo
USP<151>	Pyrogen Test
WS 310.1	Central sterile supply department (CSSD)-Part 1: Management standard

WS 310.2	Central sterile supply department (CSSD)-Part 2: Standard for operating 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
YY/T 0802	Processing of medical devices–Information to be provided by the medical device manufacturer
YY/T 1302.2	Physical requirements and microbiological performance of ethylene oxide sterilization—Part 2: Microbiological aspects
YY/T 1495	Microbiological test method for demonstrating cleaning and disinfecting efficacy
YY/T 1623	Test method of effectiveness of sterilization processes for reusable medical devices