CERTIFICATE OF ACCREDITATION

This is to attest that

EPINTEK GUIYANG LTD.

NO.1, 4TH FLOOR, BUILDING 16.18, NO. 7888, TONGCHENG AVENUE, BAIYUN DISTRICT
GUIYANG, 550016, CHINA

Testing Laboratory TL-926

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 22, 2024

IAS ACCREDITED

International Accreditation Service
Issued under the authority of IAS management

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

EPINTEK GUIYANG LTD.

www.epintek.com

Contact Name Forest Yu **Contact Phone** +86 851 8461 8453

Accredited to ISO/IEC 17025:2017 *Effective Date August 22, 2024*

Biological	
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 455-4	Medical gloves for single use Part 4: Requirements and testing for shelf-life determination
EN 13726	Test methods for wound dressings — Aspects of absorption, moisture vapour transmission, waterproofness and extensibility
EN 13868	Catheters - Test methods for kinking of single lumen catheters and medical tubing
EN ISO 20696	Sterile urethral catheters for single use Section 6: Specific requirements
EN ISO 20697	Sterile drainage catheters and accessory devices for single use Section 6: Specific requirements
GB/T 16886.7	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
GB/T 16886.12	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
GB/T 16886.17	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances
GB/T 16886.18	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
ISO 5367	Anaesthetic and respiratory equipment - Breathing sets and connectors Section 6: Design requirements
ISO 7864	Sterile hypodermic needles for single use - Requirements and test methods Section 4.3: Cleanliness Section 4.4: Limits for acidity or alkalinity

	Section 4.6: Size designation Section 4.7: Colour coding Section 4.8: Needle hub Section 4.9: Needle cap Section 4.10: Needle tube Section 4.11: Needle point Section 4.12: Bond between hub and needle tube Section 4.13: Latency of lumen Section 4.14: Sharps injury protection
ISO 7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use Section 6.2: Limits for acidity or alkalinity Section 8: Tolerance on graduated capacity Section 9: Graduated scale Section 10: Barrel Section 11: Plunger stopper/Plunger assembly Section 12: Nozzle Section 13: Performance Section 13.1: Dead space Section 13.2: Freedom from air and liquid leakage past plunger stopper Section 13.3: Force to operate the piston Section 13.4: Fit of plunger stopper/plunger in barrel
ISO 7886-2	Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps Section 6: Limits for acidity or alkalinity Section 9: Tolerance on graduated capacity Section 10: Graduate scale Section 11: Syringe design Section 12: Piston/plunger assembly Section 13: Nozzle Section 14.1: Dead space Section 14.2: Freedom from air and liquid leakage past the plunger stopper Section 14.3: Short-term flow rate error Section 14.5: Syringe Compliance
ISO 8536-4	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed Section7.1: Particulate contamination Section 7.2: Leakage Section 7.3: Test for tensile strength Section 7.4: Closure-piercing device

	Section7.5: Air-inlet device Section7.6: Tubing Section7.7: Fluid filter Section 7.8: Drip chamber and drip tube Section7.9: Flow regulator Section7.10: Flow rate of infusion set Section 7.11: Injection site Section7.12: Male conical fitting Section7.13: Protective Caps
ISO 8536-8	Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion apparatus Section 6.1: Particulate contamination Section 6.2: Tensile strength Section 6.3: Leakage Section 6.4: Male conical fitting Section 6.5: Injection site Section 6.6: Fluid filter Section 6.7: Flow rate of infusion fluid Section 6.8: Closure-piercing device Section 6.9: Air-inlet device Section 6.10: Drip chamber and drip tube Section 6.11: Tubing Section 6.12: Flow regulator Section 6.13: Protective Caps Section 6.14: Storage volume
ISO 8536-12	Infusion equipment for medical use - Part 12: Check valves for single use Section 6.2: Leakage
ISO 8536-13	Infusion equipment for medical use - Part 13: Graduated flow regulators for single use with fluid contact Section 6.1: Graduated scale Section 6.2: Particulate contamination Section 6.3: Test for tensile strength Section 6.4: Leakage Section 6.5: Flow rates
ISO 8836	Suction catheters for use in the respiratory tract Section 6.6: Performance requirements
ISO 9377-2	Water quality — Determination of hydrocarbon oil index — Part 2: Method using solvent extraction and gas chromatography

ISO 9626	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods Section 5.2: Surface Finish and Visual Appearance Section 5.3: Cleanliness Section 5.4: Limits for Acidity and Alkalinity Section 5.5: Size designation Section 5.6: Dimensions Section 5.8: Stiffness Section 5.9: Resistance to Breakage Section 5.10: Resistance to corrosion
ISO 10993-7	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
ISO 10993-12	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
ISO 10993-17	Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents
ISO 10993-18	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
ISO 18562-2	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
ISO 18562-3	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic substances
ISO 18562-4	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate
ISO 19227	Implants for surgery — Cleanliness of orthopedic implants — General requirements
ISO 20696	Sterile urethral catheters for single use Section 6: Specific requirements
ISO 20697	Sterile drainage catheters and accessory devices for single use Section 6: Specific requirements
USP 643	Total Organic Carbon
USP 665	Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products
USP 1665	Characterization and Qualification of Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products

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