



CERTIFICATE OF ACCREDITATION

This is to attest that

EPINTEK HEFEI LTD.

C1#7TH FLOOR, NATIONAL HEALTH BIG DATA INDUSTRIAL PARK, KONGQUETAI ROAD XIYOU ROAD,
HIGH-TECH ZONE
HEFEI, 230031, CHINA

Testing Laboratory TL-1043

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 February 2, 2024



A handwritten signature in black ink, reading "Raj Nathan".

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

EPINTEK HEFEI LTD.

www.epintek.com

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Accredited to ISO/IEC 17025:2017

Effective Date February 2, 2024

Mechanical	
ASTM D256	Standard Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics
ASTM D638	Standard Test Method for Tensile Properties of Plastics
ASTM F382	Standard Specification and Test Method for Metallic Bone Plates
ASTM F384	Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices
ASTM F543	Standard Specification and Test Methods for Metallic Medical Bone Screws
ASTM F648	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
ASTM F897	Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws
ASTM F1264	Standard Specification and Test Methods for Intramedullary Fixation Devices
ASTM F1541	Standard Specification and Test Methods for External Skeletal Fixation Devices
ASTM F1717	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ASTM F1798	Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
ASTM F1800	Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
ASTM F1814	Standard Guide for Evaluating Modular Hip and Knee Joint Components
ASTM F1820	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
ASTM F1875	Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
ASTM F2009	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses

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ASTM F2077	Test Methods for Intervertebral Body Fusion Devices
ASTM F2193	Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
ASTM F2267	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
ASTM F2345	Standard Test Methods for Determination of Cyclic Fatigue Strength of Ceramic Modular Femoral Heads
ASTM F2580	Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis
ASTM F2706	Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model
ASTM F2790	Standard Practice for Static and Dynamic Characterization of Motion Preserving Lumbar Total Facet Prostheses
GB/T 1040.1	Plastics—Determination of tensile properties— Part 1: General principles
GB/T 1843	Plastics—Determination of izod impact strength
GB/T 23101.4	Implants for surgery—Hydroxyapatite—Part 4: Determination of coating adhesion strength
ISO 180	Plastics — Determination of Izod impact strength
ISO 527-1	Plastics — Determination of tensile properties — Part 1: General principles
ISO 6475	Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods
ISO 7206-4	Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties and performance of stemmed femoral components
ISO 7206-6	Implants for surgery — Partial and total hip joint prostheses — Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components
ISO 7206-10	Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads
ISO 7206-12	Implants for surgery — Partial and total hip joint prostheses — Part 12: Deformation test method for acetabular shells
ISO 7206-13	Implants for surgery — Partial and total hip joint prostheses — Part 13: Determination of resistance to torque of head fixation of stemmed femoral components
ISO 12189	Implants for surgery — Mechanical testing of implantable spinal devices — Fatigue test method for spinal implant assemblies using an anterior support

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ISO 13779-4	Implants for surgery — Hydroxyapatite — Part 4: Determination of coating adhesion strength
ISO 14801	Dentistry — Implants — Dynamic loading test for endosseous dental implants
ISO 14879-1	Implants for surgery — Total knee-joint prostheses — Part 1: Determination of endurance properties of knee tibial trays
ISO 22214	Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for cyclic bending fatigue of monolithic ceramics at room temperature
ISO 23146	Fine ceramics (advanced ceramics, advanced technical ceramics) — Test methods for fracture toughness of monolithic ceramics — Single-edge V-notch beam (SEVNB) method
ISO/TS 13498	Dentistry — Torsion test of implant body/connecting part joints of endosseous dental implant systems
YY 0017	Implants for osteosynthesis—Metallic bone plates
YY 0018	Implants for osteosynthesis—Metallic bone screws
YY/T 0119.1	Spinal implants—Components used in the surgical fixation of the spinal skeletal system—Part 1: General requirements
YY/T 0119.2	Spinal implants—Components used in the surgical fixation of the spinal skeletal system—Part 2: Metallic spinal screws
YY/T 0119.3	Spinal implants—Components used in the surgical fixation of the spinal skeletal system—Part 3: Metallic spinal plates
YY/T 0119.4	Spinal implants—Components used in the surgical fixation of the spinal skeletal system—Part 4: Metallic spinal rods
YY/T 0119.5	Spinal implants—Components used in the surgical fixation of the spinal skeletal system—Part 5: Test method for measure the static and fatigue bending strength of metallic screws
YY/T 0342	Implants for surgery - Determination of bending strength and stiffness of bone plates
YY/T 0521	Dentistry—Implants—Dynamic fatigue test for endosseous dental implants
YY/T 0591	Implants for orthosynthesis—Metallic lockable intramedullary nail
YY/T 0662	Implants for surgery—Metal bone screws with asymmetrical thread and spherical under-surface—Mechanical requirements and test methods
YY/T 0809.4	Implants for surgery—Partial and total hip joint prostheses— Part 4: Determination of endurance properties and performance of stemmed femoral components
YY/T 0809.6	Implants for surgery—Partial and total hip joint prostheses—Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components

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YY/T 0809.10	Implants for surgery—Partial and total hip joint prostheses— Part 10: Determination of resistance to static load of modular femoral heads
YY/T 0809.12	Implants for surgery—Partial and total hip joint prostheses— Part 12: Deformation test method for acetabular shells
YY/T 0809.13	Implants for surgery—Partial and total hip joint prostheses— Part 13: Determination of resistance to torque of head fixation of stemmed femoral components
YY/T 0810.1	Implants for surgery—Total knee-joint prostheses—Part 1: Determination of endurance properties of knee tibial trays
YY/T 0856	Implants for orthosynthesis—Metallic angled fixation device
YY/T 0857	Standard test methods for spinal implant constructs in a vertebrectomy model
YY/T 0959	Spinal implants—Test methods for mechanical property of intervertebral body fusion devices
YY/T 0960	Spinal implants— Standard test method for measuring load induced subsidence of intervertebral body fusion device under static axial compression
YY/T 0961	Standard guide for evaluating the static and fatigue properties of interconnection mechanisms and subassemblies used in spinal arthrodesis implants
YY/T 1430	Standard test method for small punch testing of ultra-high molecular weight polyethylene used in surgical implants
YY/T 1503	Implants for surgery—Test method for determining the bending fatigue properties of metallic bone plates
YY/T 1504	Implants for surgery—Test method for determining the axial pullout strength of metallic bone screws
YY/T 1505	Implant for surgery—Test method for determining the self-tapping performance of metallic bone screws
YY/T 1506	Implants for surgery—Test method for driving torque of metallic bone screws
YY/T 1560	Spinal implant—Standard test methods for occipital-cervical and occipital-cervical-thoracic implant constructs in a vertebrectomy model
YY/T 1655	Implants for osteosynthesis—Standard test method for measuring fretting corrosion of osteosynthesis plates and screws
Metallurgy	
ASTM F1044	Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
ASTM F1147	Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings

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ASTM F1160	Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
ASTM F1854	Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
ASTM F1978	Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
ISO 16429	Implants for surgery — Measurements of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods
YY/T 0988.11	Coatings of surgical implants—Part 11: Tension testing method of calcium phosphate coating and metallic coatings
YY/T 0988.12	Coatings of surgical implants—Part 12: Shear testing method of calcium phosphate coating and metallic coatings
YY/T 0988.13	Coatings of surgical implants—Part 13: Test method for shear and bending fatigue testing of calcium phosphate and metallic and calcium phosphate/metallic coating
YY/T 0988.14	Coatings of surgical implants—Part 14: Stereological evaluation method of porous coatings
YY/T 0988.15	Coatings of surgical implants—Part 15: Test method for abrasion resistance testing of metallic thermal spray coatings
YY/T 1552	Implants for surgery—Measurements of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods
Physical	
ASTM F2003	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air
ASTM F2052	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2119	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2182	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2213	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
GB/T 10610	Geometrical Product Specifications (GPS)— Surface texture: Profile method— Rules and procedures for the assessment of surface texture

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YY/T 0809.2	Implants for surgery—Partial and total hip joint prostheses— Part2: Articulating surfaces made of metallic, ceramic and plastics materials
YY/T 0987.2	Implants for surgery—Magnetic resonance compatibility—Part 2: Magnetically induced displacement force test method
YY/T 0987.3	Implants for surgery—Magnetic resonance compatibility—Part 3: Evaluation of MR image artifacts from passive implants
YY/T 0987.4	Implants for surgery—Magnetic resonance compatibility—Part 4: Radio frequency induced heating on or near passive implants test method
YY/T 0987.5	Implants for surgery—Magnetic resonance compatibility—Part 5: Magnetically induced torque test method