



INTERNATIONAL  
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# CERTIFICATE OF ACCREDITATION

*This is to attest that*

**ORTHOTEK SHANGHAI CO., LTD.**

NO. 158 GUANGYAN ROAD  
SHANGHAI 200072, CHINA

**Testing Laboratory TL-735**

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 April 23, 2025



*International Accreditation Service*  
Issued under the authority of IAS management

Visit [www.iasonline.org](http://www.iasonline.org) for current accreditation information.

# SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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## ORTHOTEK SHANGHAI CO., LTD.

**Contact Name** Dr. Eddie Hua

**Contact Phone** +86-21-5662-7661

*Accredited to ISO/IEC 17025:2017*

*Effective Date April 23, 2025*

Physical	
ASTM D256	Standard Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics
ASTM F1044-05 (YY/T 0988.12)	Standard test method for shear testing of calcium phosphate coatings and metallic coatings
ASTM F1147-05 (YY/T 0988.11)	Standard test method for tension testing of calcium phosphate and metallic coatings
ASTM F1160 (YY/T 0988.13)	Standard test method for shear and bending fatigue testing of calcium phosphate and metallic medical and composite calcium phosphate metallic coatings
ASTM F1223 (YY/T 1765-2020)	Standard test method for determination of total knee replacement constraint
ASTM F1264-16 (YY/T 0591)	Standard specification and test methods for intramedullary fixation devices
ASTM F1541-02	Standard specification and test methods for external skeletal fixation devices
ASTM F1717 (YY/T 0857)	Standard test methods for spinal implant constructs in a vertebrectomy model
ASTM F1798 (YY/T 0961)	Standard test methods for evaluating the static and fatigue properties of interconnection mechanisms and subassemblies used in spinal arthrodesis implants
ASTM F1800 (YY/T 0810.1)	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 (YY/T 1720)	Standard test method for determining the forces for disassembly of modular acetabular devices
ASTM F1829-16	Standard test method for static evaluation of anatomic glenoid locking mechanism in shear
ASTM F1854-15 (YY/T 0988.14 ISO 4287, ISO 4288, GB/T10610)	Standard test method for stereological evaluation of porous coatings on medical implants
ASTM F1875-98	Standard practice for fretting corrosion testing of modular implant interfaces: hip femoral head-bore and cone taper interface
ASTM F1877	Standard Practice for Characterization of Particles

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ASTM F1978 (YY/T 0988.15)	Standard test method for measuring abrasion resistance of metallic thermal spray coatings by using the taber abraser
ASTM F2003-02	Standard practice for accelerated aging of ultra-high molecular weight polyethylene after gamma irradiation in air
ASTM F2009	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
ASTM F2025-06	Standard practice for gravimetric measurement of polymeric components for wear assessment
ASTM F2028-14	Standard test methods for dynamic evaluation of glenoid loosening or disassociation
ASTM F2052 (YY/T 0987.2)	Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment
ASTM F2077 (YY/T 0959)	Test methods for intervertebral body fusion devices
ASTM F2118	Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials
ASTM F2193-14 (YY/T 0119.1-5)	Standard specifications and test methods for components used in the surgical fixation of the spinal skeletal system
ASTM F2267 (YY/T 0960)	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 static and cyclic fatigue strength of ceramic modular femoral heads
ASTM F2346 (YY/T 1559)	Standard test methods for static and dynamic characterization of spinal artificial discs
ASTM F2423-11 (YY/T 1563)	Standard guide for functional, kinematic, and wear assessment of total disc prostheses
ASTM F2502 (YY/T 0509)	Absorbable plates and screws for internal fixation implants
ASTM F2514-08 (YY/T 0859)	Standard guide for finite element analysis (FEA) of metallic vascular stents subjected to uniform radial loading
ASTM F2582-14	Standard test method for impingement of acetabular prostheses
ASTM F2606-08 (YY/T 0858)	Standard guide for three-point bending of balloon expandable vascular stents and stent systems
ASTM F2624	Standard test method for static, dynamic, and wear assessment of extra-discal single level spinal constructs
ASTM F2665	Standard Specification for Total Ankle Replacement Prosthesis
ASTM F2694	Standard Practice for Functional and Wear Evaluation of Motion-Preserving Lumbar Total Facet Prostheses
ASTM F2706-08 (YY/T 1560)	Standard test methods for occipital-cervical and occipital-cervical-thoracic spinal implant constructs in a vertebrectomy model

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ASTM F2722-15	Standard practice for evaluating mobile bearing knee tibial baseplate rotational stops
ASTM F2723-13a	Standard test method for evaluating mobile bearing knee tibial baseplate/bearing resistance to dynamic disassociation
ASTM F2724-08	Standard test method for evaluating mobile bearing knee dislocation
ASTM F2777 (YYT 1736-2020)	Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion
ASTM F2790	Standard Practice for Static and Dynamic Characterization of Motion Preserving Lumbar Total Facet Prostheses
ASTM F2942-13	Standard guide for in vitro axial, bending, and torsional durability testing of vascular stents
ASTM F2979-14	Standard guide for characterization of wear from the articulating surfaces in retrieved metal-on-metal and other hard-on-hard hip prostheses
ASTM F2996	Standard practice for finite element analysis (FEA) of non-modular metallic orthopedic hip femoral stems
ASTM F3014-14	Standard test method for penetration testing of needles used in surgical sutures
ASTM F3047M	Standard Guide for High Demand Hip Simulator Wear Testing of Hard-on-hard Articulations
ASTM F3090	Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement
ASTM F3129-16	Standard guide for characterization of material loss from conical taper junctions in total joint prostheses
ASTM F3140	Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements
ASTM F3210	Standard Test Method for Fatigue Testing of Total Knee Femoral Components Under Closing Conditions
ASTM F382 (YY/T 1503, YY/T 0017, YY/T 0342)	Standard specification and test method for metallic bone plates
ASTM F384 (YY/T 0856)	Standard specifications and test methods for metallic angled orthopedic fracture fixation devices
ASTM F543 (YY/T 1504, YY/T 1505, YY/T 1506, YY/T 0018)	Standard specification and test methods for metallic medical bone screws
ASTM F561-13	Standard practice for retrieval and analysis of medical devices, and associated tissues and fluids
ASTM F564-10	Standard specification and test methods for metallic bone staples
ASTM F648	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants (only clause A1.4)

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ASTM F732-00	Standard test method for wear testing of polymeric materials used in total joint prostheses
ASTM F897-02	Standard test method for measuring fretting corrosion of osteosynthesis plates and screws
ASTM G99	Standard test method for wear testing with a pin-on-disk apparatus
ISO 11491:2017	Implants for surgery — Determination of impact resistance of ceramic femoral heads for hip joint prostheses
ISO 12189	Implants for surgery — mechanical testing of implantable spinal devices — fatigue test method for spinal implant assemblies using an anterior support
ISO 14242-1 (YY/T 0651.1)	Implants for surgery — wear of total hip-joint prostheses —part 1: loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test
ISO 14242-2 (ASTM F1714-96, YY/T 0651.2)	Implants for surgery — wear of total hip-joint prostheses —part 2: methods of measurement
ISO 14242-3 (YY/T 0651.3)	Implants for surgery — wear of total hip-joint prostheses —part 3: loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test
ISO 14242-4	Implants for surgery -- Wear of total hip-joint prostheses -- Part 4: Testing hip prostheses under variations in component positioning which results in direct edge loading
ISO 14243-1 (YY/T 1426.1)	Implants for surgery — wear of total knee-joint prostheses — part 1: loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test
ISO 14243-2 (YY/T 1426.2)	Implants for surgery — wear of total knee-joint prostheses —part 2: methods of measurement
ISO 14243-3 (YY/T 1426.3)	Implants for surgery — wear of total knee-joint prostheses — part 3: loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test
ISO 14243-5	Implants for surgery — Wear of total knee prostheses Part 5: Durability performance of the patellofemoral joint
ISO 14704	Fine ceramics (advanced ceramics, advanced technical ceramics) -- Test method for flexural strength of monolithic ceramics at room temperature
ISO 14801	Dentistry — implants — dynamic fatigue test for endosseous dental implants
ISO 14879-1 (YY/T 0810.1)	Implants for surgery — total knee-joint prostheses part 1: determination of endurance properties of knee tibial trays
ISO 16402 (YY/T 1429)	Implants for surgery — acrylic resin cement — flexural fatigue testing of acrylic resin cements used in orthopaedics
ISO 17853	Wear of implant materials — Polymer and metal wear particles — Isolation and characterization

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ISO 18192-1	Implants for surgery — wear of total intervertebral spinal disc prostheses — part 1: loading and displacement parameters for wear testing and corresponding environmental conditions for test
ISO 18192-2	Implants for surgery — wear of total intervertebral spinal disc prostheses — part 2: nucleus replacements
ISO 20501	Fine ceramics (advanced ceramics, advanced technical ceramics) -- Weibull statistics for strength data
ISO 22214	Fine ceramics (advanced ceramics, advanced technical ceramics) -- Test method for cyclic bending fatigue of monolithic ceramics at room temperature
ISO 22622	Implants for surgery — Wear of total ankle-joint prostheses — Loading and displacement parameters for wear-testing machines with load or displacement control and corresponding environmental conditions for test
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 25539-1 (YY/T 0663.1)	Cardiovascular implants -- Endovascular devices -- Part 1: Endovascular prostheses
ISO 25539-2 (YY/T 0663.2)	Cardiovascular implants -- Endovascular devices -- Part 2: Vascular stents
ISO 5833 (YY/T 0459)	Implants for surgery — acrylic resin cements
ISO 5834-3 (YY/T 0772.3)	Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 2: Moulded forms
ISO 6475 (YY/T 0662)	Implants for surgery -- Metal bone screws with asymmetrical thread and spherical under-surface -- Mechanical requirements and test methodsISO 7206-4 (YY/T 0809.4)
ISO 7206-10 (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
ISO 7206-12 (YY/T 0809.12)	Implants for surgery -- partial and total hip joint prostheses -- part 12: deformation test method for acetabular shells
ISO 7206-13 (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
ISO 7206-6 (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
ISO 9626 (YY/T 18457)	Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods
ISO/TS 13498	Dentistry — torsion test of implant body/connecting part joints of endosseous dental implant systems
PI-Acetabular Instruments*	Determination of acetabular reamers wear resistance and cutting performance

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YY/T 1430	Standard test method for small punch testing of ultra-high molecular weight polyethylene used in surgical implants
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*\*Note: Laboratory-developed method*

