



# CERTIFICATE OF ACCREDITATION

*This is to attest that*

## **BEFITLAB TEST TECHNOLOGY SHANGHAI CO., LTD.**


NO. 230, ALLEY 2999, BAOAN ROAD, JIADING DISTRICT  
SHANGHAI 201801, PEOPLE'S REPUBLIC OF CHINA

**Testing Laboratory TL-787**

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 March 24, 2020



  
\_\_\_\_\_  
**President**

# SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | [www.iasonline.org](http://www.iasonline.org)

## BEFITLAB TEST TECHNOLOGY SHANGHAI CO., LTD.

[www.website.com](http://www.website.com)

**Contact Name** Xu Zhu

**Contact Phone** +86-13816352718

*Accredited to ISO/IEC 17025:2017*

*Effective Date March 24, 2020*

<b>Physical</b>	
AAMI TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
ASTM D5992	Standard Guide for Dynamic Testing of Vulcanized Rubber and Rubber-Like Materials Using Vibratory Methods
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 F561	Standard practice for retrieval and analysis of medical devices, and associated tissues and fluids
ASTM F564	Standard specification and test methods for metallic bone staples
ASTM F732	Standard test method for wear testing of polymeric materials used in total joint prostheses phosphate metallic coatings
ASTM F897	Standard test method for measuring fretting corrosion of osteosynthesis plates and screws
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
ASTM F1160	Standard test method for shear and bending fatigue testing of calcium phosphate and metallic medical and composite calcium phosphate metallic coatings
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 methods for evaluating the static and fatigue properties of interconnection mechanisms and subassemblies used in spinal arthrodesis implants
ASTM F2028	Standard test methods for dynamic evaluation of glenoid loosening or disassociation

# SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | [www.iasonline.org](http://www.iasonline.org)

ASTM F2052	Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment
ASTM F2077	Test methods for intervertebral body fusion devices
ASTM F2132	Standard specification for puncture resistance of materials used in containers for discarded medical needles and other sharps
ASTM F2183	Standard test method for small punch testing of ultra-high molecular weight polyethylene used in surgical implants
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 static and cyclic fatigue strength of ceramic modular femoral heads
ASTM F2346	Standard test methods for static and dynamic characterization of spinal artificial discs
ASTM F2423	Standard guide for functional, kinematic, and wear assessment of total disc prostheses
ASTM F2502	Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants
ASTM F2514	Standard guide for finite element analysis (FEA) of metallic vascular stents subjected to uniform radial loading
ASTM F2582	Standard test method for impingement of acetabular prostheses
ASTM F2606	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 F2706	Standard test methods for occipital-cervical and occipital-cervical-thoracic spinal implant constructs in a vertebrectomy model
ASTM F2722	Standard practice for evaluating mobile bearing knee tibial baseplate rotational stops
ASTM F2723	Standard test method for evaluating mobile bearing knee tibial baseplate/bearing resistance to dynamic disassociation
ASTM F2724	Standard test method for evaluating mobile bearing knee dislocation
ASTM F2942	Standard guide for in vitro axial, bending, and torsional durability testing of vascular stents
ASTM F2979	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	Standard test method for penetration testing of needles used in surgical sutures

# SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | [www.iasonline.org](http://www.iasonline.org)

ASTM F3129	Standard guide for characterization of material loss from conical taper junctions in total joint prostheses
ASTM G99	Standard test method for wear testing with a pin-on-disk apparatus
EN 149	Respiratory protective devices-Filtering half masks to protect against particles-Requirements, testing, marking
EN 13795-1	Surgical clothing and drapes-Requirements and test methods Part 1: Surgical drapes and gowns
EN 14126	Protective clothing-Performance requirements and tests methods for protective clothing against infective agents
EN 14683	Medical face masks - Requirements and test methods
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
ISO 5832	Part1-part12 Implants for surgery-Metallic materials
ISO 5833	Implants for surgery — acrylic resin cements
ISO 6508-1	Metallic materials — Rockwell hardness test Part 1: Test method (scales A,B,C,D,E,F,G,H,K,N,T)
ISO 6892-1	Metallic materials - Tensile testing - Part 1: Method of test at room Temperature
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 9585	Implants for surgery--Determination of bending strength and stiffness of bone plates
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	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	Implants for surgery — wear of total hip-joint prostheses —part 2: methods of measurement
ISO 14242-3	Implants for surgery — wear of total hip-joint prostheses —part 3: loading and displacement parameters for orbital bearing type wear

# SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | [www.iasonline.org](http://www.iasonline.org)

	testing machines and corresponding environmental conditions for test
ISO 14243-2	Implants for surgery — wear of total knee-joint prostheses —part 2: methods of measurement
ISO 14243-3	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 14801	Dentistry — implants — dynamic fatigue 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 16402	Implants for surgery — acrylic resin cement — flexural fatigue testing of acrylic resin cements used in orthopaedics
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 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/TS 13498	Dentistry — torsion test of implant body/connecting part joints of endosseous dental implant systems