



CERTIFICATE OF ACCREDITATION

This is to attest that

ZHEJIANG BIOMED TESTING TECHNOLOGY LIMITED COMPANY

ROOM 201, BUILDING 7, SHANGHAI JIAOTONG UNIVERSITY (JIAXING) SCIENCE AND TECHNOLOGY PARK, NO.321 JIA CHUANG ROAD, XIUZHOU DISTRICT 314011, JIAXING CITY, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

Testing Laboratory TL-1023

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 January 16, 2022



A handwritten signature in black ink that reads 'Raj Nathan'.

President

Visit www.iasonline.org for current accreditation information.

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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ZHEJIANG BIOMED TESTING TECHNOLOGY LIMITED COMPANY

Contact Name Balance Cai

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Accredited to ISO/IEC 17025:2017

Effective Date January 16, 2022

ASTM D638	Standard test method for tensile properties of plastics
ASTM D790	Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials
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 bone screws
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
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 F1223	Standard test method for determination of total knee replacement constraint
ASTM F1264	Standard specification and test methods for intramedullary fixation devices
ASTM F1378	Standard specification for shoulder prostheses
ASTM F1541	Standard specification and test methods for external skeletal fixation devices
ASTM F1580	Standard specification for titanium and titanium-6 aluminum-4 vanadium alloy powders for coatings of surgical implants

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ASTM F1714	Standard guide for gravimetric wear assessment of prosthetic hip designs in simulator 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 F1829	Standard test method for static evaluation of anatomic glenoid locking mechanism in shear
ASTM F1854	Standard test method for stereological evaluation of porous coatings on medical implants
ASTM F1875	Standard practice for fretting corrosion testing of modular implant interfaces: hip femoral head-bore and cone taper interface
ASTM F1978	Standard test method for measuring abrasion resistance of metallic thermal spray coatings by using the taber abraser
ASTM F2003	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	Standard practice for gravimetric measurement of polymeric components for wear assessment
ASTM F2028	Standard test methods for dynamic evaluation of glenoid loosening or disassociation
ASTM F2033	Standard specification for total hip joint prosthesis and hip endoprosthesis bearing surfaces made of metallic, ceramic, and polymeric materials
ASTM F2077	Test methods for intervertebral body fusion devices
ASTM F2083	Standard specification for knee replacement prosthesis
ASTM F2118	Standard test method for constant amplitude of force controlled fatigue testing of acrylic bone cement materials
ASTM F2180	Standard specification for metallic implantable strands and cables
ASTM F2183	Standard test method for small punch testing of ultra-high molecular weight polyethylene used in surgical implants

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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 F2502	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 F2580	Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis
ASTM F2582	Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components
ASTM F2606	Standard guide for three-point bending of balloon expandable vascular stents and stent systems
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	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 F2777	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 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 orthopaedic hip femoral stems
ASTM F3014	Standard test method for penetration testing of needles used in surgical sutures

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ASTM F3047M	Standard guide for high demand hip simulator wear testing of hard-on-hard articulations
ASTM F3129	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 F3161	Standard test method for finite element analysis (FEA) of metallic orthopaedic total knee femoral components under closing conditions
ASTM F3334	Standard Practice for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Tibial Components
ASTM G99	Standard test method for wear testing with a pin-on-disk apparatus
GB 23101.2	Implants for surgery hydroxyapatite part 2: Coatings of hydroxyapatite
GB 23101.4	Implants for surgery hydroxyapatite part 4: determination of coating adhesion strength
GB/T 228.1	Metallic materials tensile testing part 1: Method of test at room temperature
GB/T 1040.1	Plastics determination of tensile properties part 1: General principles
GB/T 9341	Plastics determination of flexural properties
GB/T 10610	Geometrical product specifications (GPS) surface texture: profile method. rules and procedures for the assessment of surface texture
GB/T 18457	Stainless steel needle tubing for the manufacture of medical devices
ISO 178	Plastics determination of flexural properties
ISO 527-1	Plastics determination of tensile properties part 1: General principles
ISO 4287	Geometrical product specifications (GPS) — surface texture: profile method — terms, definitions and surface texture parameters
ISO 4288	Geometrical product specifications (GPS) — surface texture: profile method — rules and procedures for the assessment of surface texture
ISO 5833	Implants for surgery acrylic resin cements
ISO 5834-3	Implants for surgery Ultra-high- molecular-weight polyethylene part 3 Accelerated ageing methods
ISO 5836	Implants for surgery Metal bone plates Holes corresponding to screws with asymmetrical thread and spherical under-surface
ISO 5837-1	Implants for surgery Intramedullary nailing systems part 1: Intramedullary nails with cloverleaf or V-shaped cross-section
ISO 5838-1	Implants for surgery metallic skeletal pins and wires part 1: General requirements

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ISO 5838-2	Implants for surgery skeletal pins and wires part 2: Steinmann skeletal pins Dimensions
ISO 5838-3	Implants for surgery skeletal pins and wires part 3: Kirschner skeletal wires
ISO 6475	Implants for surgery metal bone screws with asymmetrical thread and spherical under-surface mechanical requirements and test methods
ISO 6892-1	Metallic materials tensile testing part 1: Method of test at room temperature
ISO 7206-1	Implants for surgery partial and total hip joint prostheses part 1: Classification and designation of dimensions
ISO 7206-2	Implants for surgery partial and total hip joint prostheses part 2: Articulating surfaces made of metallic, ceramic and plastics materials
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 7206-8	Implants for surgery partial and total hip joint prostheses part 8: Endurance performance of stemmed femoral components with application of torsion
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 7207-1	Implants for surgery components for partial and total knee joint prostheses part 1: Classification, definitions and designation of dimensions
ISO 7207-2	Implants for surgery components for partial and total knee joint prostheses part 2: Articulating surfaces made of metal, ceramic and plastics materials
ISO 9626	Stainless steel needle tubing for the manufacture of medical devices requirements and test methods
ISO 10271	Dentistry corrosion test methods for metallic materials
ISO 10334	Implants for surgery malleable wires for use as sutures and other surgical applications
ISO 11491	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

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ISO 13779-2	Implants for surgery hydroxyapatite part 2: thermally sprayed coatings of hydroxyapatite
ISO 13779-4	Implants for surgery hydroxyapatite part 4: determination of coating adhesion strength
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 testing machines and corresponding environmental conditions for test
ISO 14243-1	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	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 orbital bearing type wear testing machines and corresponding environmental conditions for test
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 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 15142-1	Implants for surgery metal intramedullary nailing systems part 1: Intramedullary nails
ISO 15142-2	Implants for surgery metal intramedullary nailing systems part 2: Locking components
ISO 15142-3	Implants for surgery metal intramedullary nailing systems part 3: Connection devices and reamer diameter measurements
ISO 16402	Implants for surgery-acrylic resin cement flexural fatigue testing of acrylic resin cements used in orthopaedics
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

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ISO 21535	Non-active surgical implants joint replacement implants specific requirements for hip-joint replacement implants
ISO 21536	Non-active surgical implants joint replacement implants specific requirements for knee-joint replacement implants
ISO 22214	Fine ceramics (advanced ceramics, advanced technical ceramics) test method for cyclic bending fatigue of monolithic ceramics at room temperature
ISO 23089-2	Implants for surgery pre-clinical mechanical assessment of spinal implants and particular requirements part 2: Spinal intervertebral body fusion devices
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 1116	Absorbable surgical suture
YY 0167	Non-absorbable surgical suture
YY 0315	Wrought titanium and titanium dental implant
YY 0346	Implants for osteosynthesis metal nail of neck fixation of femur
YY 0502	Joint replacement implants-Knee joint prostheses
YY/T 0019.1	Implants for surgery Intramedullary nailing systems part 1: Intramedullary nails with cloverleaf or V-shaped cross-section
YY/T 0119.1~5	Standard specifications and test methods for components used in the surgical fixation of the spinal skeletal system
YY 0341.1	Non-active surgical implants osteosynthesis and spinal implants part 1:Particular requirements for osteosynthesis implants
YY 0341.2	Non-active surgical implants osteosynthesis and spinal implants part 2: Particular requirements for spinal implants
YY/T 0342	Implants for surgery determination of bending strength and stiffness of bone plates
YY/T 0345.1	Implants for surgery metallic skeletal pins and wires part 1: General requirements
YY/T 0345.2	Implants for surgery skeletal pins and wires part 2: Steinmann skeletal pins Dimensions
YY/T 0345.3	Implants for surgery skeletal pins and wires part 3: Kirschner skeletal wires

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YY/T 0459	Implants for surgery acrylic resin cements
YY/T 0509	Standard specification and test methods for bioabsorbable plates and screws for internal fixation implants
YY/T 0521	Dentistry Implants dynamic fatigue test for endosseous dental implants
YY/T 0528	Dental metallic materials corrosion test methods
YY/T 0591	Standard specification and test methods for intramedullary fixation devices
YY/T 0621.2	Dentistry compatibility testing part 2: Ceramic-ceramic systems
YY/T 0651.1	Implant for surgery Wear of total hip-joint prostheses part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test
YY/T 0651.2	Implant for surgery wear of total hip-joint prostheses part 2: Methods of measurement
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
YY/T 0662	Implants for surgery – Metal bone screws with asymmetrical thread and spherical under-surface – Mechanical requirements and test methods
YY/T 0727.1	Implants for surgery metal intramedullary nailing systems part 1: Intramedullary nails
YY/T 0727.2	Implants for surgery metal intramedullary nailing systems part 2: Locking components
YY/T 0727.3	Implants for surgery metal intramedullary nailing systems part 3: Connection devices and reamer diameter measurements
YY/T 0772.3	Implants for surgery Ultra-high-molecular-weight polyethylene part 3: Accelerated ageing methods
YY/T 0809.1	Implants for surgery partial and total hip joint prostheses part 1: Classification and designation of dimensions
YY/T 0809.2	Implants for surgery partial and total hip joint prostheses Part 2: Articulating surfaces made of metallic, ceramic and plastics materials
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
YY/T 0809.8	Implants for surgery partial and total hip joint prostheses part 8: Endurance performance of stemmed femoral components with application of torsion

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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 0812	Implants for surgery metallic implantable strands and cables
YY/T 0816	Implants for surgery malleable wires for use as sutures and other surgical applications
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 0858	Standard guide for three-point bending of balloon expandable vascular stents and stent systems
YY/T 0859	Standard guide for finite element analysis (FEA) of metallic vascular stents subjected to uniform radial loading
YY/T 0919	Non-active surgical implants joint replacement implants specific requirements for knee-joint replacement implants
YY/T 0920	Non-active surgical implants joint replacement implants specific requirements for hip-joint replacement implants
YY/T 0924.1	Implants for surgery components for partial and total knee joint prostheses part 1: Classification, definitions and designation of dimensions
YY/T 0924.2	Implants for surgery components for partial and total knee joint prostheses part 2: Articulating surfaces made of metal, ceramic and plastics materials
YY/T 0959	Test methods for intervertebral body fusion devices
YY/T 0960	Standard test method for measuring load induced subsidence of intervertebral body fusion device under static axial compression
YY/T 0961	Standard test method for evaluating the static and fatigue properties of interconnection mechanisms and subassemblies used in spinal arthrodesis implants
YY/T 0963	Joint replacement implants shoulder prostheses
YY/T 0988.2	Coatings of surgical implants part 2: titanium and titanium-6 aluminum-4 vanadium alloy powders
YY/T 0988.11	Standard test method for tension testing of calcium phosphate and metallic coatings

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YY/T 0988.12	Standard test method for shear testing of calcium phosphate coatings and metallic coatings
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
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 1133	Instrumentation for use in association with non-active surgical implants-Metallic bone drill bits
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
YY/T 1426.2	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
YY/T 1426.3	Implants for surgery wear of total knee-joint prostheses part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test
YY/T 1429	Implants for surgery acrylic resin cement flexural fatigue testing of acrylic resin cements used in orthopaedics
YY/T 1430	Standard test method for small punch testing of ultra-high molecular weight polyethylene used in surgical implants
YY/T 1502	Spinal implants intervertebral body fusion devices
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 1559	Standard test methods for static and dynamic characterization of spinal artificial discs
YY/T 1560	Spinal implants standard test methods for occipital-cervical and occipital-cervical-thoracic implant constructs in a vertebrectomy model
YY/T 1563	Spinal implants Test method for functional, kinematic and wear assessment of total disc prostheses

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YY/T 1634	Joint replacement implants shoulder prostheses standard test methods for dynamic evaluation of glenoid loosening or disassociation
YY/T 1647	Standard test method for static evaluation of anatomic glenoid locking mechanism in shear
YY/T 1655	Implants for osteosynthesis standard test method for measuring fretting corrosion of osteosynthesis plates and screws
YY/T 1705	Implants for surgery determination of impact resistance of ceramic femoral heads for hip joint prostheses
YY/T 1714	Standard practice for finite element analysis (FEA) of non-modular metallic orthopaedic hip femoral stems
YY/T 1715	Implants for surgery. Ceramic materials based on yttria-stabilized tetragonal zirconia(Y-TZP)
YY/T 1720	Standard test method for determining the forces for disassembly of modular acetabular devices
YY/T 1736	Standard test method for evaluating tibial insert endurance and deformation under high flexion
YY/T 1746	Absorbable surgical suture test method for breaking strength in vitro hydrolytic degradation
YY/T 1762	Standard test method for cyclic fatigue of metal tibial tray components of unicondylar knee joint replacements
YY/T 1765	Standard test method for determination of total knee replacement constraint
YY/T 1779	Dentistry Orthodontic anchor screws