



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

APPLUS (JIANGSU) TESTING CO., LTD.
 No. 7 Xinyong Road, Wujin District
 Changzhou, Jiangsu, People's Republic of China, 213161
 Luis Guelbenzu Phone: 34 667 16 7967

MECHANICAL

Valid To: June 30, 2027

Certificate Number: 4106.04

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following test on medical devices and materials:

<u>Test:</u>	<u>Test Methods:</u>
Medical devices:	
Metallic spinal screws Torsion properties Driving torque Axial pull-out load Bending properties Metallic spinal plates Static tests Fatigue tests Metallic spinal rods Static tests Fatigue tests	ASTM F2193, YY/T 0119.1
Spinal internal fixation system	
Static Compression Bending Test Static Tension Bending Test Static Torsional Test Procedure for Fatigue Testing	ASTM F1717, YY/T 0857
Static A-P load (Fx) Transverse load (Fy) Axial gripping capacity (Fz) Transverse moment (Mx) Flexion-extension moment (My) Axial torque (Mz) Tulip/shank disassociation (Fx) Fatigue strength	ASTM F1798, YY/T 0961
Metallic spinal screws	
Torsional performance Bending performance Driving torque Axial pullout strength	YY/T 0119.2
Static tests Fatigue tests	YY/T 0119.5

<u>Test:</u>	<u>Test Methods:</u>
Metallic spinal plates Static tests Fatigue tests	YY/T 0119.3
Metallic lockable intramedullary nail Static four-point bend Static torsional Bending fatigue Bending fatigue of locking screws Bending structural stiffness Fatigue strength at N cycles Failure strength Yield strength Structural stiffness Ultimate strength	ASTM F1264, YY/T 0591
Metallic spinal rods Static tests Fatigue tests	YY/T 0119.4
Intervertebral body fusion devices	
Static tests Dynamic tests	ASTM F2077, YY/T 0959
Static axial compression	ASTM F2267, YY/T 0960
Metallic Bone Plates	
Standard test method for single cycle bend testing of metallic bone plates	ASTM F382, YY/T 0342
Standard test method for determining the bending fatigue properties of metallic bone plates	ASTM F382, YY/T 1503
Bending strength and equivalent bending stiffness Fatigue properties Hardness Surface defects Surface roughness Appearance Geometric property	YY 0017
Metallic Medical Bone Screws	
Torsional properties	ASTM F543, ISO 6475, YY/T 0662, YY 0018
Axial pullout strength	ASTM F543, YY/T 1504, YY 0018
Insertion torque Removal torque	ASTM F543, YY/T 1506, YY 0018
Driving torque Axial pullout load Self-Tapping performance	ASTM F543, YY/T 1505, YY 0018
Hardness Surface defects Surface roughness Appearance Dimensions	YY 0018
Constant amplitude bending Fatigue Pull-out fixation strength Soft tissue fixation strength Elastic static bending	ASTM F564



<u>Test:</u>	<u>Test Methods:</u>
Porous coatings Mean Coating Thickness Volume Percent Void Mean Void Intercept Length	ASTM F1854, YY/T 0988.14
Thermal spray coatings Abrasion resistance test of metallic thermal spray coatings	ASTM F1978, YY/T 0988.15
Hip-joint prostheses Resistance to static load of modular femoral heads	ISO 7206-10, YY/T 0809.10
Fatigue of neck region of stemmed femoral components	ISO 7206-6, YY/T 0809.6
Fatigue of stemmed femoral components	ISO 7206-4, YY/T 0809.4
Acetabular shells deformation	ISO 7206-12, YY/T 0809.12
Resistance to torque of head fixation of stemmed femoral components	ISO 7206-13, YY/T 0809.13
Determination of endurance properties of stemmed femoral components without application of torsion	ISO 7206-3
Endurance performance of stemmed femoral components with application of torsion	ISO 7206-8
Axial disassembly force	ASTM F2009
Disassembly force of modular acetabular devices	YY/T 1720, ASTM F1820
Total hip-joint prostheses wearing	ISO 14242-1, YY/T 0651.1, ISO 14242-3, YY/T 0651.3
Measurement	ISO 14242-2, YY/T 0651.2
Testing hip prostheses under variations in component positioning which results in direct edge loading	ISO 14242-4
Femoral components of total hip joint prostheses Plastics acetabular components Femoral prostheses for partial joint replacements Bipolar heads Metal and ceramic acetabular components of total hip joint prostheses	ISO 7206-2, YY/T 0809.2
Appearance Surface defects Surface roughness Dimensions of important parts and tolerance Static mechanical properties Dynamic properties	YY 0118
Designation of dimensions	YY/T 0809.1
On-Axis Fatigue Test Method Off-Axis Fatigue Test Method	ASTM F2345, YY/T 1855
Finite element analysis (FEA) of non-modular metallic orthopedic hip femoral stems	ASTM F2996
Fatigue Testing of Acetabular Devices for Total Hip Replacement	ASTM F3090
Impact Resistance of Ceramic Femoral Heads for Hip Joint Prostheses	ISO 11491, YY/T 1705
Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices	ASTM F1714

<u>Test:</u>	<u>Test Methods:</u>
Structural Requirements Shear Strength Tensile Strength Abrasion Resistance of Plasma Spray Thermal Coatings	ASTM F2068
Dynamic Impingement Between Femoral and Acetabular Hip Components	ASTM F2582
Hip Simulator Wear Testing of Hard-on-Hard Articulations	ASTM F3047M
Calcium Phosphate and Metallic Coatings	
Tensile properties	ASTM F1147, YY/T 0988.11
Shear tests	YY/T 0988.12, YY/T 0988.13, ASTM F1044
Shear and bending fatigue tests	ASTM F1044, ASTM F1160, YY/T 0988.13
Angled Fixation Devices The relevant compression bending properties The relevant bending properties The relevant angled device bending fatigue The relevant sideplate bending fatigue properties	ASTM F384, YY/T 0856
External Skeletal Fixation Devices External skeletal fixator connectors The in-plane compressive properties External skeletal fixator joint External skeletal fixator pins External skeletal fixator subassemblies External skeletal fixator-bone constructs	ASTM F1541, YY/T 1782
Knee-joint prostheses	
Tibial trays fatigue	ISO 14879-1, ASTM F1800, YY/T 0810.1
Degrees of constraint	ASTM F1223, YY/T 1765
Endurance and Deformation Under High Flexion	YY/T 1736, ASTM F2777
Implants for surgery— Wear of total	ISO 14243-1, YY/T 1426.1
Knee-joint prostheses—Part 2: Methods of measurement	ISO 14243-2, YY/T 1426.2
Implants for surgery — Wear of total knee-joint prostheses-Part3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test	ISO 14243-3, YY/T 1426.3
Durability performance of the patellofemoral joint	ISO 14243-5
Durability performance of the patellofemoral joint	YY/T 1762
Dynamic fatigue properties Mechanical properties	YY 0502
Fatigue Testing of Total Knee Femoral Components Under Closing Conditions	ASTM F3210
Metal or Ceramic Femoral Component Metal or Ceramic Tibial Joint Component Plastic Tibial and Patellar Component	YY/T 0924.2



<u>Test:</u>	<u>Test Methods:</u>
Evaluating mobile bearing knee tibial baseplate rotational stops	ASTM F2722
Axial Engagement Force Torsional Axial force Shear force Bending force Torsion force Cyclic Fatigue Properties	ASTM F1814
Mechanical Strength Corrosion Resistance Polymeric Component Oxidation Resistance Fatigue Performance of Total Knee Tibial Tray Fatigue Performance of Unicompartmental Knee Tibial Tray Durability and Deformation Performance of Mobile Platforms Range of Relative Angular Motion of Knee Prostheses Constraint Force Testing of Knee Prostheses High Flexion Constraint Testing Reliability of Modular Knee Joint Component Connections Wear Performance of Knee Prostheses Morphology and Mechanical Properties Morphology and Mechanical Properties Dimensions Appearance and Surface Roughness of Metallic Articulating Surfaces Appearance and Surface Roughness of Non-metallic Articulating Surfaces	ASTM F2083
Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements	ASTM F3140
Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs Compression bending Tensile bending Torsion Compression bending fatigue Torsion fatigue	ASTM F2706, YY/T 1560
Implants for surgery—Ultra-high-molecular-weight polyethylene—Moulded forms	
Morphology assessment method	ISO 5834-3, ISO 5834-5, ASTM F2003, YY/T 0772.3, YY/T 0772.5
Accelerated aging methods	ISO 5834-3, ISO 5834-5, ASTM F2003, YY/T 0772.3, YY/T 0772.5, YY/T 0681.1
Non-absorbable surgical suture Breaking strength Needle and suture connection strength Marking Wire Diameter	YY 0167



<u>Test:</u>	<u>Test Methods:</u>
Shoulder Prostheses	
Dynamic Evaluation of Glenoid Loosening or Disassociation	ASTM F2028, YY/T 1634
Evaluation test of glenoid locking mechanism static shear	YY/T 1647
All Prosthetic glenoid components shall be capable of withstanding sustained static and dynamic physiological forces Dimensions Articulating surface finishes	ASTM F1378, YY/T 0963
Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear	ASTM F1829
Ankle-joint prostheses	
Wear rate	ISO 22622
Load Fatigue of Tibial Tray Components Load Fatigue of Tibial Bearing Surface Components Contact Area and Contact Pressure Range of Motion Constraint Forces Static and Dynamic Shear, Bending, and Tensile Tests Wear Morphology, and Mechanical Properties Morphology and Coating Strength	ASTM F2665
Non-active surgical implants and joint replacement implants Surface finish of metallic or ceramic implants articulating on ultra-high-molecular-weight polyethylene (UHMWPE) Surface finish of metallic or ceramic partial implants Surfaces of convex, spherically-conforming metallic or ceramic implants articulating on UHMWPE Surfaces of spherically-conforming metallic or ceramic partial implants Surfaces of concave, spherically-conforming UHMWPE components Metal surfaces Plastic surfaces Ceramic surfaces	ISO 21534, GB/T 12417.2
Acrylic resin cements	
Determination of doughing time of liquid-powder mixture of cement intended for dough usage	ISO 5833
Determination of compressive strength of polymerized cement Determination of bending modulus and bending strength of polymerized cement	ISO 5833, YY 0459



<u>Test:</u>	<u>Test Methods:</u>
Flexural fatigue properties	ISO 16402, YY/T 1429
Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials	ASTM F2118
Osteosynthesis plates and screws Fretting corrosion	ASTM F897, YY/T 1655
Modular implant Interfaces Fretting corrosion	ASTM F1875
Medical instruments of stainless steel	
Boiling test in deionized water Boiling test in 0,9 % NaCl solution Test in 0,3 % sodium chloride solution of austenitic steels Test with citric acid solution for austenitic steels Autoclave test	ISO 13402
Thermal test	ISO 13402, YY/T 0149
Autoclave test for corrosion Boiling water test for corrosion Sodium chloride solution test method Citric acid solution test method	YY/T 0149
Metallic U-shaped nails Test for mechanical property of metallic U-shaped nails	YY/T 1781
Osteosynthesis and spinal implants	
Hardness Static and/or dynamic mechanical properties Surface defects Surface roughness Appearance Dimensions of important parts Complexation properties	YY 0341.1, YY 0341.2
Coating	YY 0341.2
Metallic implantable strands and cables Surface finishing and treatment Dimensions Mechanical properties	YY/T 0812
Dentistry—Orthodontic anchor screws	
Dimensions Torsional performance	ISO 19023, YY/T 1779
Surface roughness	YY/T 1779
Diaphragm for orthodontic aligner Appearance Smell Dimensions Wear resistance Mechanical properties	YY/T 1819
Dental implant	
Torsion test	ISO/TS 13498
Microstructure Dimensions Surface properties Cleaning Mechanical properties	YY 0315



Test:	Test Methods:
Dynamic loading test	ISO 14801, YY/T 0521
Dental implant attachments Appearance Dimensions Surface roughness Surface defects Microstructure Attachment Fatigue limits	YY/T 0520
Dental Metallic materials	
Shape and dimensions Tensile properties Bending properties Microstructure Surface quality Grain size	GB/T 13810
Mechanical Properties	GB 17168
Dentistry—Water-based cements	
Film thickness (luting cements only)	ISO 9917-1, YY 0271.1, ISO 9917-2, YY 0271.2
Setting time-Class 1 and Class 3 materials only Flexural strength	ISO 9917-1, YY 0271.1 YY 0272
Net setting time Compressive strength Working time	ISO 9917-1, YY 0271.1
Setting time at 37 °C Compressive strength at 24h Film thickness	ISO 3107, YY 0272
Dentistry—Compatibility testing	
Thermal shock resistance	ISO 9693, YY/T 0621.2
De-bonding/crack-initiation test (zirconia-porcelain only) Thermocycling test with fixed temperature interval	ISO 9693
Dentistry-Polymer-based restorative materials	
Film thickness, luting materials Working time, Class 1 and Class 3 restorative materials, excluding luting materials Working time, Class 1 and Class 3 luting materials Setting time, Class 1 materials Setting time, Class 3 materials Depth of cure, Class 2 materials Water sorption and solubility	ISO 4049, YY 1042
Proof strength of 0.2 % non-proportional extension Elongation after fracture Young's modulus Density	ISO 22674, GB 17168

<u>Test:</u>	<u>Test Methods:</u>
Sterile dental injection needles for single use Colour coding Connecting fastness Needle tip patency Appearance Needle Needle tip Hub	YY/T 0587
Sterile hypodermic needles for single use	
Straightness Connecting fastness Patency Needle seat and sheath coordination Needle Hub	GB 15811
Cleanliness Colour coding	GB 15811, ISO 7864
Needle tip	GB 15811, ISO 7885
Limits for acidity or alkalinity (pH) Size designation Needle hub Needle cap Needle tube Bond between hub and needle tube	ISO 7864
Union between hub and needle Dimensions Butt end Socket depth Needle tip	ISO 7885
Dental-root-casai obturating points Points Length Size designation and taper Physical integrity Colour coding	YY/T 0495
Dental polymer-based adhesives for restoratives Appearance Film thickness Adhesive strength Working time, Class 1 and Class 3 materials Setting time, Class 1 and Class 3 materials	YY/T 0518
Dentistry—Brackets and tubes for use in orthodontics Measurement of dimensions	ISO 27020, YY/T 0915
Stainless steel needle tubing for the manufacture of medical devices Dimensions Size designation Surface finish and visual appearance Cleanliness Stiffness Resistance to breakage Resistance to corrosion	ISO 9626, GB/T 18457



Test:	Test Methods:
Dentistry—Drills used in dental implant surgery Appearance Dimensions Surface roughness Hardness Run-out Torque Machinability Reprocessing	YY/T 1064
Dental collagen membrane Appearance Dimensions Structure property Hydrophilia Tensile strength Elongation after fracture Tear force	YY/T 1794
Single-use sterile rubber surgical gloves Dimensions Watertightness Tensile properties	ISO 10282, GB/T 7543
Single-use medical rubber examination glove Dimensions Water tightness Tensile properties	ISO 11193-1, GB 10213
Hydroxyapatite Calculation of coating adhesion strength	ISO 13779-4
Osteoinductive calcium phosphate bioceramics Appearance and dimensions	GB/T 41672
Metallic fixation screw for femur neck Mechanical properties Surface defects Surface roughness Appearance Dimensions Complexation properties	YY/T 0346
Ceramic modular femoral heads Ceramic modular femoral heads fatigue property tests	YY/T 1855
Suture anchor Appearance Surface defects Dimensions Fracture force Fatigue properties Surface roughness Hardness Corrosion resistance Needle and suture connection strength Suture anchor mechanical properties	YY/T 1867
Suture Tensile tests	YY/T 1832



<u>Test:</u>	<u>Test Methods:</u>
Absorbable surgical suture Appearance Suture diameter Breaking strength Needle and suture connection strength Length Wire Diameter	YY 1116
Geometrical product specifications (GPS) - Surface texture	
Geometrical product specifications (GPS)—Surface texture: Profile—Part3: Specification operators	ISO 21920-3, GB/T 10610
Indication of surface texture	ISO 21920-1
Terms, definitions and surface texture parameters	ISO 21920-2
High speed dental needle Shape Dimensions Radial circular run-out Neck strength	YY 0761.1
Wires for use in orthodontics Dimensions Mechanical properties	ISO 15841, YY/T 0625
Dentistry rotary instruments Shape of the working part Diameter of the working part Neck diameter Dimensions of the mandrel Length of working part Overall length Angle of the taper of the working part Run-out of the working part	ISO 8325, YY/T 0874
Dimensions of the shanks	ISO 8325, YY/T 0874, ISO 3823-1
Neck strength test	ISO 8325, YY/T 0874, ISO 3823-1, ISO 3823-2
Run-out	ISO 3823-1, ISO 3823-2
Corrosion resistance Surface roughness Dimensions of working part and number of blades	ISO 3823-1
Dimensions and number of blades Cleaning, disinfection and sterilization	ISO 3823-2
Dentistry shanks for rotary instruments	
Dimensions	ISO 1797, YY/T 0967
Hardness Tensile test Stability against swelling and chemicals for plastic shanks Marking	ISO 1797

Test:	Test Methods:
Dentistry—Endodontic instrument Type 1: Standard instruments Type 2: Taper instruments Type 3: Non-taper instruments Type 4: Non-uniform taper instruments Type 5: Shape instruments Dimensions Mechanical requirements Reprocessing	ISO 3630-1, YY/T 0803.1
Dentistry—Endodontic instruments—Enlargers Dimensions, designation and number of blades Mechanical properties requirements	YY/T 0803.2
Dentistry—Root-canal instruments—Condensers Dimensional requirements for standard-type pluggers and spreaders Dimensional requirements for taper size pluggers and taper size spreaders luggers and spreaders fitted in long handles (hand-type instruments) Mechanical requirements	YY 0803.3
Dentistry—Root-canal instruments—Auxiliary instruments Dimensions Colour designation and size marking with rings Mechanical properties requirements Corrosion resistance Heat effects of sterilization	YY/T 0803.4
Dentistry—Endodontic instruments—Shaping and cleaning instruments Dimensions Mechanical Chemical Colour coding	ISO 3630-5, YY/T 0803.5
Prefabricated Dental Post Appearance Dimensions Internal Porosity	YY/T 0517
Metal Bone Pin	
Mechanical Properties	ISO 5838-1, YY/T 0345.1
Surface Quality	YY/T 0345.1
Dimensions Ends	ISO 5838-2, ISO 5838-3, YY/T 0345.2, YY/T 0345.3
Tip and Blunt End	ISO 5838-3, YY/T 0345.3
Intramedullary Nail Surface Dimensions	YY/T 0019.2



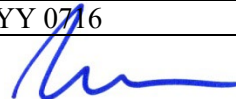
Test:	Test Methods:
Interbody Fusion Cage Static and dynamic torsion tests of cervical fusion apparatus Static axial compression and shear tests Dynamic axial compression and shear tests Settlement test Hardness Dimensions Surface Defects Surface Roughness Appearance	YY/T 1502
Stomatology surgical instruments Pull-out Test Torque Test	YY/T 0281
External Fixator Appearance Surface Roughness of Metal Components Dimensions Functional Performance Corrosion Resistance Mechanical Properties	YY/T 0508
Orthopedic U-shaped Nail Dimensional Marking Tolerances Tensile Properties Surface	YY/T 0956
Orthopedic Surgical Guide Mechanical Properties Corrosion Resistance Dimensions Surface Quality Functional Performance	YY/T 1845
Bioabsorbable Internal Fixation Plate Yield Strength Torsional Strength Axial Pull-out Force Insertion Torque Consideration of Geometric Dimensions Flexural Properties	YY/T 0509
Prefabricated Cranial Plate for Neurosurgical Implants Dimensions and Tolerances	YY/T 0928
Moldable Prefabricated Cranial Plate for Neurosurgical Implants Dimensions and Tolerances	YY/T 0917
Suture button Appearance Surface roughness Surface defect Dimensions Hardness Corrosion resistance Breaking Force Mechanical Properties of Loop Fixation Plate	YY/T 1927



Test:	Test Methods:
Medical Endoscope Endoscopic Instruments Grasping Forceps Hardness Consistency Check of Surface and Internal Material Appearance Dimensions Functional Performance Durability (Applicable to Non-disposable Products)	YY/T 0940
Spinal artificial discs	
Static and dynamic characterization	ASTM F2346, YY/T 1559
Standard guide for functional, kinematic, and wear assessment	ASTM F2423, YY/T 1563
Fatigue test method for spinal implant assemblies using an anterior support	ISO 12189
Vascular stents Finite Element Analysis (FEA) of Metallic Vascular Stents	ASTM F2514, YY/T 0859
Pin-on-Disk Test Wear and Friction Testing with a Pin-on-Disk or Ball-on-Disk Apparatus	ASTM G99
Dental elevators Maximum overall length Vickers hardness of the working end Surface finish Resistance against autoclaving Resistance against corrosion Resistance against thermal exposure Union between the working end and handle	ISO 15087-1
Artificial teeth for dental prostheses Dimensions of teeth Colour and blending of shades Surface finish Porosity and other defects Anchorage Resistance to thermal shock Bonding to denture base polymer Resistance to blanching, distortion and crazing Dimensional stability	ISO 22112
Surgical Instruments Corrosion of Surgical Instruments	ASTM F1089
Metallic Implantable Strands and Cables Joints Dimensional Requirements Mechanical Requirements Surface Finish	ASTM F2180
Single Level Spinal Constructs	
Wear of total intervertebral spinal disc prostheses	ISO 18192-1
Nucleus replacements	ISO 18192-2
Materials:	
Metallic materials	
Tensile tests	ASTM E8/E8M, ISO 6892-1, GB/T 228.1



Test:	Test Methods:
Vickers hardness test	ISO 6507-1, GB/T 4340.1, GB/T 16534
Brinell hardness test	ISO 6506-1, GB/T 231.1
Rockwell hardness test	ISO 6508-1, GB/T 230.1
The average grain size	ASTM E112, GB/T 6394
Liquid penetrant inspection of metallic surgical implants	ISO 9583, YY/T 0343
Metallic materials—Compression test method at room temperature	GB/T 7314
Apparent grain size	ISO 643
Fatigue testing—Axial force-controlled method	ISO 1099, GB/T 3075
Surface roughness Dimensions Warping deformation Mechanical properties Impurities and porosity Properties of metal-ceramic system Debonding/crack initiation test	YY/T 1702
Properties of metal-ceramic system	YY 0621.1
Bend Test for Metal Materials	GB/T 232
Shore Hardness	ISO 868, ASTM D2240, GB/T 2411
Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials	ASTM E466
Bend Testing of Metallic Flat Materials for Spring Applications Involving Static Loading	ASTM E855, YB/T 5349
Torque-Controlled Fatigue Testing	ISO 1352, GB/T 12443
Fatigue Testing – Statistical Planning and Analysis of Data	ISO 12107, GB/T 24176
Tension Testing Wrought and Cast Aluminum- and Magnesium-Alloy Products	ASTM B557
Compression Testing at Room Temperature	ASTM E9
Oral materials Testing of adhesion	YY/T 0519
Dentistry—Polymer-based filling, restorative and cementing materials Film thickness of the bonding material Working hours of Class I and Class III repair materials (except adhesive materials) Working hours of Class I and Class III adhesive materials Curing time of Class I materials Curing time of Class III materials Curing depth of Class II materials (except adhesive materials) Flexural strength Water absorption value and dissolution value	YY 1042
Dentistry—Ceramic materials	
Uniformity Flexural strength	GB 30367, YY 0716
Freedom from extraneous materials Fracture toughness	GB 30367
Free from Foreign Contaminants	YY 0716



Test:	Test Methods:
De-bonding/crack-initiation test (zirconia-porcelain only)	YY/T 0621.2
Hydroxyapatite	
Adhesion strength to substrate	GB 23101.2
Coating adhesion strength	GB 23101.4
Hydroxyapatite coated Types and structure of dental implants Dimension accuracy Appearance HA Tensile adhesive strength of coating and titanium substrate Dynamic fatigue test	YY 0304
Implants for surgery—Forged stainless steel material Mechanical properties	GB 4234.1, YY 0605.9
Implants for surgery—Cobalt-chromium-molybdenum casting alloy Mechanical properties	GB 4234.4
Pure titanium and titanium alloy materials for surgical implants Microstructure Mechanical properties	GB 23102
Plastic	
Compressive Properties	GB/T 1041
Flexural Properties	ASTM D790
Bending properties	ISO 178, GB/T 9341
Izod impact strength	ISO 180, GB/T 1843
Impact properties	ASTM D256
Tensile properties	ISO 527-1, ISO 527-2, ISO 527-3, ISO 527-4, ISO 527-5, GB/T 1040.1, GB/T 1040.2, GB/T 1040.3, GB/T 1447, ASTM D638, ISO 5834-2, GB/T 19701.2
Particulate matter Double-notched Izod impact strength	ISO 5834-2, GB/T 19701.2
Ultra-high molecular weight polyethylene used in surgical implants Small punch testing	YY/T 1430
Polyetheretherketone(PEEK) polymers for Surgical Implant Applications Tensile properties Bending properties Impact strength, notched Izod	ASTM F2026, YY/T 0660
Nickel-Titanium Shape Memory Alloy for Surgical Implants Mechanical properties	GB/T 24627
Forged and Cast Parts for Orthopedic Joint Implants Mechanical Properties Surface Quality Casting Shape and Dimensions	YY 0117.1, YY 0117.3

Test:	Test Methods:
Ultra-High Molecular Weight Polyethylene, UHMWPE	
Tensile Strength at Break and Yield Tensile Strength Cantilever Beam Impact Strength Elongation at Break Elastic Modulus or Young's Modulus Compressive Modulus Punching Load Limit	YY/T 0811
Foreign Matter Requirements Morphology Requirements Tensile Strength Elongation Izod Impact Strength	ASTM F648
Advanced Ceramics	
Uniaxial Strength Data and Estimating Weibull Distribution Parameters	ASTM C1239
Monotonic Equiaxial Flexural Strength	ASTM C1499
Polymeric materials used in total joint prostheses Wear testing	ASTM F732
Ceramic	
Wear Fracture toughness	ISO 6474-1
Biaxial flexural strength 4-point flexural strength Hardness Cycle fatigue	ISO 6474-1, ISO 6474-2, YY/T 1294.2
Weibull modulus Fracture toughness Accelerated Aging	ISO 6474-2, YY/T 1294.2
Flexural strength of monolithic ceramics	ISO 14704
Weibull statistics for strength data	ISO 20501
Physical properties	ISO 22214
Dental materials	
Implantable materials for bone filling and augmentation in oral and maxillofacial surgery	ISO 22794
Test method- DIN.	ISO/TS 14569-2
Size designation and taper Physical integrity	ISO 6877



The laboratory is accredited for the test methods listed above. The accredited test methods are used in determining compliance with the material specifications listed below; however, the inclusion of these material specifications on this Scope does not confer laboratory accreditation to the material specifications. Inclusion of these material specifications on this Scope also does not confer accreditation for every method embedded within the specification. Only the methods listed above on this Scope are accredited.

ASTM: ASTM F2887, ASTM F2580, ASTM F2606, ASTM F1357, ASTM F1672, ASTM F2624, ASTM E606/606M, ASTM C1292

GB: GB 10213, GB 15811, GB 23101.1, GB/T 23101.6, GB/T 1463, GB/T 33613, GB/T 33614, GB/T 13682, GB/T 26077, GB/T 15248, GB/T 4337, GB/T 36983

ISO: ISO 10139-1, ISO 10477, ISO 13779-2, ISO 13779-6, ISO 14233, ISO 16061, ISO 20795-1, ISO 20795-2, ISO 21535, ISO 21536, ISO 25539-1, ISO 25539-2, ISO 3964, ISO 26443, ISO 3800, ISO 1143, ISO 23146, ISO 15732, ISO 18756

YY: YY 0270.1, YY 0710, YY 0714.1, YY 0877, YY 1116, YY/T 0043, YY/T 0105, YY/T 0270.2, YY/T 0663.1, YY/T 0663.2, YY/T 0726, YY/T 0874, YY/T 0919, YY/T 0920, YY/T 0967, YY/T 1615, YY/T 1851, YY/T 1746, YY/T 1701, YY/T 0172, YY/T 0858, YY/T 0966, YY/T 0727.1, YY/T 0727.2





Accredited Laboratory

A2LA has accredited

APPLUS (JIANGSU) TESTING CO., LTD.

Jiangsu, People's Republic of China

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



Presented this 7th day of July 2025.

A blue ink signature of Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 4106.04
Valid to June 30, 2027

For the tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.