



CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board

500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

JTL America
3205 Clairmont Ct., Ste. B
Fort Wayne, IN 46808

has been assessed by ANAB
and meets the requirements of international standard

ISO/IEC 17025:2005

while demonstrating technical competence in the fields of

TESTING

Refer to the accompanying Scope of Accreditation for information regarding the types of calibrations and/or tests to which this accreditation applies.

L2167

Certificate Number



ANAB Approval

Certificate Valid: 12/16/2017-01/9/2020
Version No. 002 Issued: 12/16/2017



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. 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).



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

JTL America
3205 Clairmont Ct., Ste. B
Fort Wayne, IN 46808
Kevin Knight
260-489-1444

TESTING

Valid to: January 9, 2020

Certificate Number: L2167

Mechanical

Table with 4 columns: Specific Tests and/or Properties Measured, Specification, Standard, Method, or Test Technique, Items, Materials or Product Tested, and Key Equipment or Technology. It lists four types of mechanical testing: Tension & Compression Monotonic Testing, Force Controlled Cyclic Testing, Displacement Controlled Cyclic Testing, and Torsional Monotonic Testing.

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Torque Controlled Cyclic Testing (-225 to 225) Nm (0 to 270) degrees (0 to 5) Hz	Customer supplied specifications Laboratory developed specifications approved by the client	Mechanical components: medical, automotive, aerospace, heavy vehicle, agricultural, defense, and consumer products	
Fracture Toughness Testing (-250 000 to 250 000) N (Up to 5) in	ASTM E399 ASTM B645 ASTM E1820	All Metal Alloys	
Axial Fatigue Testing (Strain and Stress) (-250 000 to 250 000) N	ASTM E466 ASTM E606	All Metal Alloys	

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. L2167.
2. This laboratory offers commercial testing service.

JTL America has demonstrated technical competency to perform ISO/IEC 17025:2005 accredited testing activities per the test technologies identified in the table above and the test methods identified below per the attached annex 1.

Annex 1 – ISO/IEC 17025 Accredited Test Methods

ASTM Test Methods:

- F382 Standard Specification and Test Method for Metallic Bone Plates
- F543 Standard Specification and Test Methods for Metallic Medical Bone Screws
- F564 Standard Specification and Test Methods for Metallic Bone Staples
- F1044 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- F1147 Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings
- F1160 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
- F1440 Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components without Torsion
- F1223 Standard Test Method for Determination of Total Knee Replacement Constraint
- F1264 Standard Specification and Test Methods for Intramedullary Fixation Devices



- F1612 Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion
- F1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
- F1798 Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
- F1800 Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
- F1820 Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device
- F2009 Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
- F2028 Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation
- F2077 Test Methods for Intervertebral Body Fusion Devices
- F2193 Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
- F2267 Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device under Static Axial Compression
- F2345 Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads
- F2502 Standard Specification and Test Methods for Bioabsorbable Plates and Screws for Internal Fixation Implants
- F2706 Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model
- F2777 Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion
- E8 Standard Test Methods for Tension Testing of Metallic Materials
- E9 Standard Test Methods of Compression Testing of Metallic Materials at Room Temperature
- E466 Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
- E606 Standard Test Method for Strain-Controlled Fatigue Testing
- E1820 Standard Test Method for Measurement of Fracture Toughness J_{Ic}
- E399 Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness K_{Ic} of Metallic Materials
- B645 Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness of Aluminum Alloys

ISO Test Methods:

- 7206-4 Implants for surgery -- Partial and total hip joint prostheses -- Part 4: Determination of endurance properties and performance of stemmed femoral components
- 7206-6 Implants for surgery -- Partial and total hip joint prostheses -- Part 6: Determination of endurance properties of head and neck region of stemmed femoral components
- 7206-10 Implants for surgery -- Partial and total hip-joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads
- 9585 Determination of bending strength and stiffness of bone plates
- 14801 Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants
- 6892-1 Metallic Materials -- Tensile Testing -- Part 1: Method of Test at Room Temperature

