SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT CINCINNATI
3701 Port Union Road
Fairfield, Ohio 45014
Meghan Smith Phone: 513 984 4112

MECHANICAL

Valid To: April 30, 2026 Certificate Number: 2422.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following types of tests on metallic and nonmetallic materials, components, and devices:

Test Description:	**Method(s):**
Mechanical Properties - Metals	
Cyclic Testing (-320 to 2500) °F in Air, Inert Gas, Saline; Up to 35,000 lbs; Up to 6 in Stroke; Up to 60 Hz	
Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials	ASTM E466
Strain-Controlled Fatigue Testing	ASTM E606
Fatigue Crack Growth Testing	ASTM E647
Rotating Bar Bending Fatigue Testing	ISO 1143
Monotonic & Other Mechanical Testing (-320 to 2500) °F in Air, Inert Gas, Saline; Up to 300,000 lbs; Up to 6 in Stroke	
Compression Testing	ASTM E9
Fracture Toughness Testing	ASTM B645, B646, E399, E561, E1304, E1820
Tensile	ASTM B557, E8, E21
Elastic Modulus	ASTM E111
Medical Device Testing	
Hip Devices	
Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interfaces	ASTM F1875
Acetabular Impingement	ASTM F2582
Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis	ASTM F2580
Disassembly Force - Modular Acetabular Device	ASTM F1820

Test Description:	**Method(s):**
Hip Stem Static and Dynamic	ISO 7206-3, -4, -6, -8; ASTM F2068
Hip Wear Assessment	ASTM F1714
Hip Wear Assessment	ISO 14242-2, -3
Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads	ASTM F2345
Knee Devices	
Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	ASTM F1800
Determination of Total Knee Replacement Constraint	ASTM F1223
Knee Prosthesis Replacement Testing	ASTM F2083
Patellar Prosthesis Resurfacing Testing	ASTM F1672
Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion	ASTM F2777
Total Knee Prostheses - Determination of Endurance Properties of Knee Tibial Trays	ISO 14879-1
Unicondylar Fatigue	ASTM F3140
Wear of Total Knee Prosthesis	ISO 14243-1, -2, -3
Spinal Devices	
Wear of Total Intervertebral Spinal Disc Prostheses	ISO 18192-1, -2
Expulsion Testing of Spinal Implants	MED-SPN-EXP
Fatigue Test Method for Spinal Implants	ISO 12189
Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression	ASTM F2267
Spinal Devices	
Intervertebral Body Fusion Devices	ASTM F2077
Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs	ASTM F2624
Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model	ASTM F2706
Spinal Implant Constructs	ASTM F1717
Static and Dynamic Characterization of Spinal Artificial Discs	ASTM F2346
Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	ASTM F1798
Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System	ASTM F2193[2]
Other Medical Devices & Related Materials	
Articulating Total Wrist Implant Testing	ASTM F1357
Coating Taber Abrasion	ASTM F1978

Test Description:	**Method(s):**
Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials	ASTM F2118, ISO 5833
Corrosion of Surgical Instruments	ASTM F1089
Dynamic Fatigue Test for Endosseus Dental Implants	ISO 14801
Dynamic Evaluation of Glenoid Loosening or Disassociation	ASTM F2028
Evaluation of Glenoid Locking Mechanism in Shear	ASTM F1829
Shear Testing	ASTM F1044
Porous Coating - Shear and Bending Fatigue Testing	ASTM F1160
Shoulder Prosthesis Testing	ASTM F1378
Stereological Evaluation	ASTM F1854
Tension Testing	ASTM F1147
Taper Connections of Modular Prostheses	ASTM F2009
Test Methods for Metallic Bone Staples	ASTM F564
Test Methods for External Fixation Devices	ASTM F1541
Total Ankle Replacement Testing	ASTM F2665
Total Elbow Replacement Testing	ASTM F2887
Standard Guide for Evaluating Modular Hip and Knee Joint Components	ASTM F1814
Test Method for Wear Testing with a Pin-on-Disk Apparatus	ASTM G99
Test Method for Linearly Reciprocating Ball-on-Flat Sliding Wear	ASTM G133
Metallic Bone Plates	ASTM F382, Annex A1 and A2
Single Cycle Bend Testing	
Determining the Bending Fatigue Properties	
Properties of Metallic Medical Bone Screws	ASTM F543, Annex A1, A2, A3 and A4
Torsional Properties	
Driving Torque	
Axial Pullout Strength	
Self-Tapping Performance	
Metallic Angled Orthopedic Fracture Fixation Devices	ASTM F384, Annex A1 and A2
Single Cycle Compression Bend Testing	
Determining the Bending Fatigue Properties	
Test Methods for Intramedullary Fixation Devices	ASTM F1264, Annex A1, A2, A3 and A4
Static Four-Point Bend	
Static Torsion Test	
Bending Fatigue of IMFDs	
Bending Fatigue of IMFD Locking Screws	

Test Description:	**Method(s):**
Non-active surgical implants – Mammary implants – Particular Requirements	ISO 14607 Annex C1 and C2
Mechanical Contraceptives – Reusable Natural and Silicone Rubber Contraceptive Diaphragms	ISO 8009 Annex A, C, E, and F
Hardness Testing	
Durometer Hardness of Rubber (Type A)	ASTM D2240
Specimen Preparation	
Conventional Machining, EDM Machining	ASTM E8, E466, E606, D695, D790, D2344/D2344M, D3039/D3039M, D3518/D3518M
Low Stress Grinding and Polishing	Internal Procedure MFG/QC-2007 and Customer Procedures[3]

[1]Using customer-specified methods directly related to types of tests and parameters listed above.

[2]ASTM F2193 (static testing only).

[3]Using customer-specified preparation procedures related to the testing listed.

Accredited Laboratory

A2LA has accredited

ELEMENT CINCINNATI

Fairfield, OH

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 12th day of June 2024.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2422.01
Valid to April 30, 2026

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