



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

ELEMENT CINCINNATI
 3701 Port Union Road
 Fairfield, Ohio 45014
 Justin Riebesel Phone: 513 771 2536

MECHANICAL

Valid To: April 30, 2018

Certificate Number: 2422.01

In recognition of the successful completion of the A2LA evaluation process (including compliance to R223 – Specific Requirements – GE Aviation S-400 Accreditation Program), accreditation is granted to this laboratory to perform the following tests on metallic and nonmetallic materials, components, and devices:

<u>Test Description</u>	<u>Method(s)</u>
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)	
Bend	ASTM E290
Compression Testing	ASTM E9
Creep, Creep Rupture, Stress Rupture	ASTM E139, E292
Fasteners (Axial Tensile and Hardness)	ASTM F606
Fracture Toughness Testing	ASTM B645, B646, E399, E561, E1304, E1820
Tensile	ASTM B557, E8, E21
Torque – static and dynamic (Up to 20,000 in-lbf)	BMW 90003-3

<u>Test Description</u>	<u>Method(s)</u>
Mechanical Properties – Polymers and Composites	
Cyclic Testing (-320 to 2700°F in Air, Inert Gas, Saline; Up to 300,000 lbs; Up to 6 in Stroke; Up to 60 Hz)	
Tension-Tension Fatigue	ASTM C1360, C1361, D3479/D3479M, Customer Procedures ³
Monotonic & Other Mechanical Testing (-320 to 2500°F in Air, Inert Gas, Saline; Up to 300,000 lbs; Up to 6 in Stroke)	
Bending & Flexural Properties	ASTM C1161, C1341, D790,
Compressive Properties	ASTM C1292, D695, D3410/3410M
Compressive Residual Strength	ASTM D7137/7137M
Creep Rupture, Stress Rupture	ASTM C1337
Damage Resistance to a Drop-Weight Impact Event (Dent Depth)	ASTM D7136/7136M
Tensile Properties	ASTM C1275, C1359, C1468, D638, D3039/3039M
Shear Properties	ASTM C1425, D2344/D2344M, D3518/D3518M
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
Hip Stem Static and Dynamic	ISO 7206-3, -4, -6, -8
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

<u>Test Description</u>	<u>Method(s)</u>
Knee Devices	
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
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
Intervertebral Body Fusion Devices	ASTM F2077
Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression	ASTM F2267
Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebroctomy Model	ASTM F2706
Spinal Implant Constructs	ASTM F1717
Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs	ASTM F2624
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	
Accelerated Aging of UHMW-PE After Gamma Irradiation in Air	ASTM F2003
Accelerated Aging of Sterile Barrier Systems	ASTM F1980
Articulating Total Wrist Implant Testing	ASTM F1357
Biological Tissue Testing	MED-GLP-1000 ¹
Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials	ASTM F2118



<u>Test Description</u>	<u>Method(s)</u>
Other Medical Devices & Related Materials	
Corrosion of Surgical Instruments	ASTM F1089
Dynamic Fatigue Test for Endosseous Dental Implants	ISO 14801
Dynamic Evaluation of Glenoid Loosening or Disassociation	ASTM F2028
Evaluation of Glenoid Locking Mechanism in Shear	ASTM F1829
Metallic Bone Plates	ASTM F382, Annex A1 and A2
Single Cycle Bend Testing	
Determining the Bending Fatigue Properties	
Metallic Angled Orthopedic Fracture Fixation Devices	ASTM F384, Annex A1 and A2
Single Cycle Compression Bend Testing	
Determining the Bending Fatigue Properties	
Porous Coating Testing	
Shear Testing	ASTM F1044
Shear and Bending Fatigue Testing	ASTM F1160
Shoulder Prosthesis Testing	ASTM F1378
Stereological Evaluation	ASTM F1854
Tension Testing	ASTM F1147
Properties of Metallic Medical Bone Screws	ASTM F543, Annex A1, A2, A3 and A4
Torsional Properties	
Driving Torque	
Axial Pullout Strength	
Self-Tapping Performance	
Small Punch Testing of UHMWPE	ASTM F2183
Taper Connections of Modular Prostheses	ASTM F2009
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 Methods for Metallic Bone Staples	ASTM F564
Test Methods for External Fixation Devices	ASTM F1541
Standard Guide for Evaluating Modular Hip and Knee Joint Components	ASTM F1814

<u>Test Description</u>	<u>Method(s)</u>
Metallographic Evaluation	
Preparation	ASTM E3
Banding / Orientation of Microstructure	ASTM E1268
Depth of Decarburization	ASTM E1077
Grain Size	ASTM E112
Inclusion Rating	ASTM E45, Method A
Alpha Case	MET-ALC-7100
IGA / IGO	MET-IGA-1000
Macro Etch	ASTM E340
Micro Etch	ASTM E407
Photomicrography / Light Microscopy	ASTM E883
Hardness Testing	
Brinell Hardness Testing (Scales 10/500, 2.5/187.5)	ASTM E10
Microhardness	ASTM E384
Knoop (500 gm)	
Vickers (100, 300, 500 gm)	
Rockwell Hardness (Scales B, C, 15N, 30N, 30T)	ASTM E18
Weld Qualification Testing	
Weld Procedure Qualification Testing	AWS B2.1, B4.0, D1.1, D1.2, D1.3, D1.6, D17.1; ASME IX
Welder Performance Qualification Testing	AWS B2.1, B4.0, D1.1, D1.2, D1.3, D1.6, D17.1; ASME IX
Miscellaneous	
Failure Analysis	FLR ANL 1000
Specimen Preparation	
Conventional Machining, EDM Machining	ASTM E8, E466, E606, D695, D790, D2344/D2344M, D3039/D3039M, D3518/D3518M
Low Stress Grinding and Polishing, Inertia Welding	Internal Procedure MFG/QC-2007 and Customer Procedures ⁴

¹This test method is accredited to 21 CFR 58 Good Laboratory Practice (GLP) standards per A2LA Checklist C214.

²ASTM F2193 (static testing only)

³Using customer-specified methods directly related to types of tests listed above.

⁴Using 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 17025:2005 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets R223 – Specific Requirements – GE Aviation S-400 Accreditation Program. 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 8 January 2009).

Presented this 29th day of February 2016.



A handwritten signature in blue ink, appearing to read "J. C. Bunt".

Senior Director of Quality & Communications
For the Accreditation Council
Certificate Number 2422.01
Valid to April 30, 2018

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