

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

<u>Test Description:</u>	<u>Method(s):</u>
Spinal Devices	
Intervertebral Body Fusion Devices	ASTM F2077
Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs	ASTM F2624

<u>Test Description:</u>	<u>Method(s):</u>
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 Tests	
Bending Fatigue of IMFDs	
Bending Fatigue of IMFD Locking Screws	
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
<u>Hardness Testing</u>	
Durometer Hardness of Rubber (Type A)	ASTM D2240
<u>Specimen Preparation</u>	
Conventional Machining, EDM Machining	ASTM E8, E466, E606, D695, D790, D2344/D2344M, D3039/D3039M, D3518/D3518M
Low Stress Grinding and Polishing, Inert Gas Welding	Internal Procedure MFG/QC-2007 and Customer Procedures

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

²ASTM F2193 (static testing only).

³Using 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 23rd day of May 2022.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2422.01
Valid to April 30, 2024