

## SCOPE OF ACCREDITATION TO ISO/IEC 17025017

## devices

Test Description	Method(s):
Mechanical PropertiesMetals	
Cyclic Testing	
(-320 to 2500) ℉ in Air, Inert Gas, Saline;	
Up to 35,000 lbs, Up to 6 in StrokeUp to 60 Hz	
Force Controlled Constant Amplitude Axial	ASTM E466
Fatigue Tests defletallic Materials	
StrainControlled Fatigue Testing	ASTM E606
Fatigue Crack Growth Testing	ASTM E647
Rotating Bar Bending Fatigue Testing	ISO 1143
Monotonic & Other Mechanical Testing	
(-320 to2500) F in Air, Inert Gas, Saline;	
Up to 300,000 lbs; Up to 6 in Stroke	

	E1820
Tensile	ASTM B557, E8, E21
Elastic Modulus	ASTM E111
Medical Device Testing	
Hip Devices	
Fretting Corrosion Testing of Modular Inhamt Interfaces: Hip Femoral Healthore and Cone Taper Interfaces	ASTM F1875
Acetabular Impingement	ASTM F2582

**Evaluation of Modular Connection of Proximall** 

Test Description	Method(s):
Hip Stem Static and Dynamic	ISO 72063, -4, -6, -8; ASTM F2068
Hip Wear Assessment	ASTM F1714
Hip Wear Assessment	ISO 142422, -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 JoiReplacements	ASTM F1800
Determination of Total Knee Replacement Constraint	ASTM F1223

Knee I814.2 (I0.48 r4.36 0.486 TF re f 562 (I0.

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 Bonetaples	ASTM F564
Test Methods for External Fixation Devices	ASTM F1541
Total Ankle Replacement Testing	ASTM F2665

Total Elbow Replacement Testing

Test Description	Method(s):
Non-active surgical implants Mammary implants—ParticularRequirements	ISO 14607 Anne£1 and C2
Mechanical ContraceptivesReusable Natural and SiliconeRubberContraceptiveDiaphragms	ISO 8009 Annex AC, E, and F
Hardness Testing	
DurometerHardness oRubber (Type A)	ASTM D2240
<u>SpecimerPreparation</u>	
Conventional Machining, EDM Machining	ASTM E8, E466, E606, D695, D790, D2344/D2344M, D3039/D3039M, D3518/D3518M
Low Stress Grinding and Polishing	Internal Procedure MFG/Q2007 and Customer Procedures

<sup>&</sup>lt;sup>1</sup>Using customespecified methods directly related to types of tests and parameters listed above.

<sup>&</sup>lt;sup>2</sup>ASTM F2193 (static testing only)

<sup>&</sup>lt;sup>3</sup>Using customer

## A2LA has accredited

## **ELEMENT CINCINNATI**