

Accredited Laboratory

A2LA has accredited

ELEMENT MATERIALS TECHNOLOGY

Minnetonka, MN

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).

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Presented this 15th day of April 2019.

Vice President, Accreditation Services For the Accreditation Council Certificate Number 2783.01 Valid to May 31, 2021



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT MATERIALS TECHNOLOGY

Minnetonka, Minnesota Location 5929 Baker Road, Suite 430 Minnetonka, MN 55345 Peggy Wittenberg Phone: 952-933-1152 x 49421

MECHANICAL

Valid To: May 31, 2021

Certificate Number: 2783.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on <u>medical devices</u>:

<u>Test</u>	Test Method(s)
In-Vitro Pulsatile Durability Testing of Vascular Stents	ASTM F2477;
	ISO 25539-1 (Annex D),
	ISO 7198 (Annex A)
In-vitro Axial, Bending, and Torsional Durability Testing of Vascular	ASTM F2942
Stents	
Cardiovascular Implants and Extracorporeal System – Vascular	ISO 7198 (Annex A)
Prostheses – Tubular Vascular Grafts and Vascular Patches	, , , , , ,
Circumferential Tensile Strength	
Longitudinal Tensile Strength	
Kink Diameter/Radius	
Dynamic Radial Compliance	
Medical Device Testing	
Hip Devices	
Hip Stem Static and Dynamic	ISO 7206-4, -6
Knee Devices	,
Cyclic Fatigue Testing of Metal Tibial Tray	ASTM F1800
Components of Total Knee Joint Replacements	
Spinal Devices	
Spinal Implant Constructs	ASTM F1717
Intervertebral Body Fusion Devices	ASTM F2077
Occipital-Cervical and Occipital-Cervical-Thoracic Spinal	ASTM F2706
Implant Constructs in a Vertebrectomy Model	

(A2LA Cert. No. 2783.01) 04/15/2019

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Test	Test Method(s)
Other Medical Devices and Related Materials Metallic Bone Plates Single Cycle Bend Testing Determining the Bending Fatigue Properties Dynamic Fatigue Test for Endosseus Dental Implants	ASTM F382 (Annex A1 and A2) ISO 14801
Accelerated Cyclic Polarization Corrosion Test	ASTM F2129-17B

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