



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

ELEMENT MATERIALS TECHNOLOGY CINCINNATI, INC.
 Minnetonka, Minnesota Location
 5929 Baker Road, Suite 430
 Minnetonka, MN 55345
 Peggy Wittenberg Phone: 952-933-1152 x21

MECHANICAL

Valid To: May 31, 2019

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 medical devices:

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

<u>Test</u>	<u>Test Method(s)</u>
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





Accredited Laboratory

A2LA has accredited

ELEMENT MATERIALS TECHNOLOGY CINCINNATI, INC.

Minnetonka, MN

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *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 8 January 2009).



Presented this 16th day of August 2017.

A handwritten signature in black ink, written over a horizontal line.

President and CEO
For the Accreditation Council
Certificate Number 2783.01
Valid to May 31, 2019
Revised October 18, 2017

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