



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT MATERIALS TECHNOLOGY

Minnetonka, Minnesota Location

5929 Baker Road, Suite 430

Minnetonka, MN 55345

Trevor Shad Phone: 952-933-1152 x 49421

MECHANICAL

Valid To: May 31, 2027

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>                                                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| Vascular Stents, In-vitro<br>Pulsatile Durability<br><br>Axial, Bending, and Torsional Durability Testing of Vascular Stents                                                                                 | ASTM F2477;<br>ISO 25539-1 (Annex D),<br>ISO 7198 (Annex A)<br><br>ASTM F2942 |
| Cardiovascular Implants and Extracorporeal System – Vascular Prostheses – Tubular Vascular Grafts and Vascular Patches<br>Longitudinal Tensile Strength<br>Kink Diameter/Radius<br>Dynamic Radial Compliance | ISO 7198 (Annex A)                                                            |
| Cardiovascular Implants – Endovascular Devices<br>Radial Force                                                                                                                                               | ISO 25539-1 (Annex D),<br>ISO 25539-2 (Annex D)<br>Radial Force only          |
| Medical Devices and Related Materials<br>Metallic Bone Plates Single Cycle Bend Testing Determining the Bending Fatigue Properties<br>Dynamic Fatigue Test for Endosseous Dental Implants                    | ASTM F382 <sup>1</sup> (Annex A1 and A2)<br>ISO 14801 <sup>1</sup>            |
| Accelerated Cyclic Polarization Corrosion Test                                                                                                                                                               | ASTM F2129                                                                    |

| <b><u>Test</u></b>                                                                                                                                                                                                                                                                            | <b><u>Test Method(s)</u></b>  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Intravascular Catheters<br>Test method for corrosion resistance (Annex A)<br>Method for determining peak tensile force (Annex B)<br>Test Method for liquid leakage under pressure (Annex C)<br>Test for burst pressure under static conditions (Annex F)                                      | ISO 10555-1 Annex A, B, C, F  |
| Sterile single-use intravascular introducers, dilators and guidewires<br>Surface Examination<br>Corrosion Resistance (Annex B)<br>Peak Tensile Force (Annex C)<br>Fracture Test (Annex F)<br>Flex Test (Annex G)<br>Method for determining peak tensile force of guidewires (Annex H)         | ISO 11070 Annex B, C, F, G, H |
| Sterile drainage catheters and accessory devices for single use<br>Test method for determining kink stability<br>Test method for corrosion resistance<br>Test Method for determining peak tensile force of connections<br>Test method for determining peak tensile force of drainage Catheter | ISO 20697 Annex A, B, D, E    |

<sup>1</sup> Equipment for this test is calibrated to ASTM E4 but the dynamic verification of the equipment per ASTM E467 and/or ISO 4965 is not performed.



# 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).



Presented this 3<sup>rd</sup> day of July 2025.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 2783.01  
Valid to May 31, 2027

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