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, 2025 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:

Test	Test Method(s)
Vascular Stents, In-vitro	
Pulsatile Durability	ASTM F2477; ISO 25539-1 (Annex D), ISO 7198 (Annex A)
Axial, Bending, and Torsional Durability Testing of Vascular Stents	ASTM F2942
Cardiovascular Implants and Extracorporeal System – Vascular Prostheses – Tubular Vascular Grafts and Vascular Patches Longitudinal Tensile Strength Kink Diameter/Radius Dynamic Radial Compliance	ISO 7198 (Annex A)
Cardiovascular Implants – Endovascular Devices Radial Force	ISO 25539-1 (Annex D), ISO 25539-2 (Annex D) Radial Force only
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[1] (Annex A1 and A2) ISO 14801[1]
Accelerated Cyclic Polarization Corrosion Test	ASTM F2129

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Test	Test Method(s)
Intravascular Catheters Test method for corrosion resistance (Annex A) Method for determining peak tensile force (Annex B) Test Method for liquid leakage under pressure (Annex C) 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 Surface Examination Corrosion Resistance (Annex B) Peak Tensile Force (Annex C) Fracture Test (Annex F) Flex Test (Annex G) 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 Test method for determining kink stability Test method for corrosion resistance Test Method for determining peak tensile force of connections Test method for determining peak tensile force of drainage Catheter	ISO 20697 Annex A, B, D, E

[1] 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 14th day of June 2023.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 2783.01
Valid to May 31, 2025

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