

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

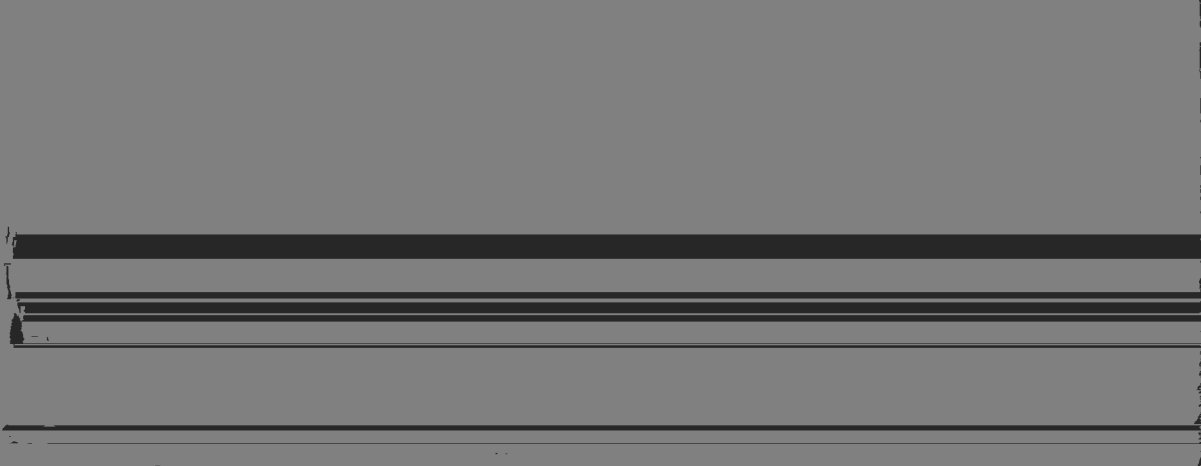
ELEMENT MATERIALS TECHNOLOGY  
Minnetonka, Minnesota Location  
5929 Baker Road, Suite 430  
Minnetonka, MN 55345  
Peggy Wittenberg Phone: 952-933-1152 x 49421

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



<u>Test</u>	<u>Test Method(s)</u>
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	ISO 7198 (Annex A)
Longitudinal Tensile Strength	
Kink Diameter/Radius	
Dynamic Radial Compliance	
Cardiovascular Implants – Endovascular Devices	
Radial Force	ISO 25539-1 (Annex D), ISO 25539-2 (Annex D)

**Test**

**Test Method(s)**

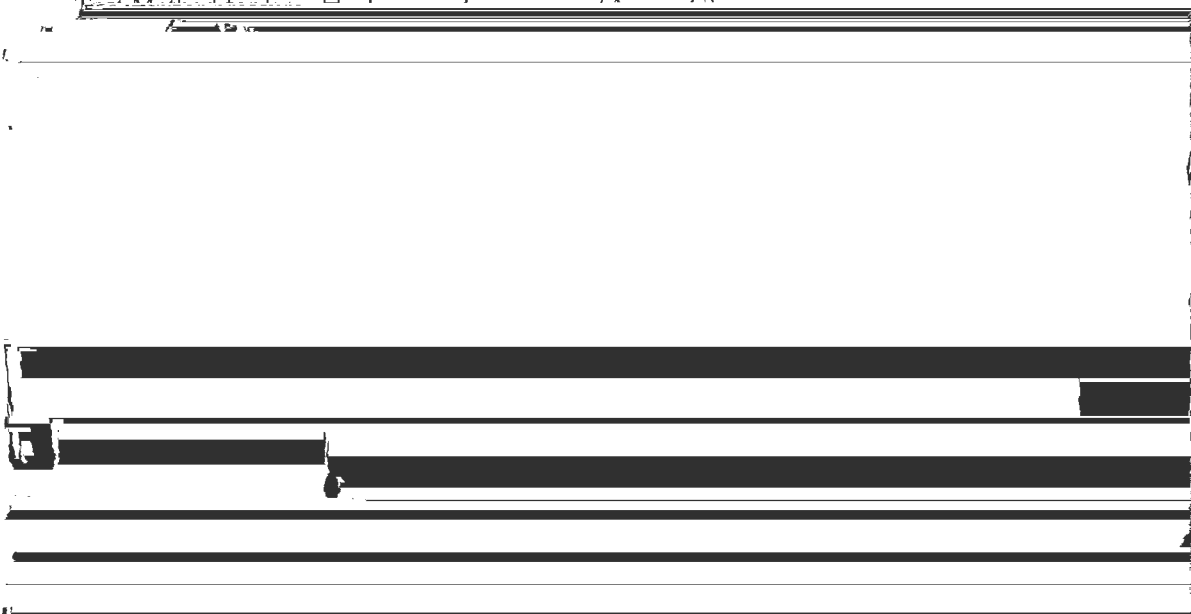
Intravascular Catheters

ISO 10555-1 Annex A, B, C, F

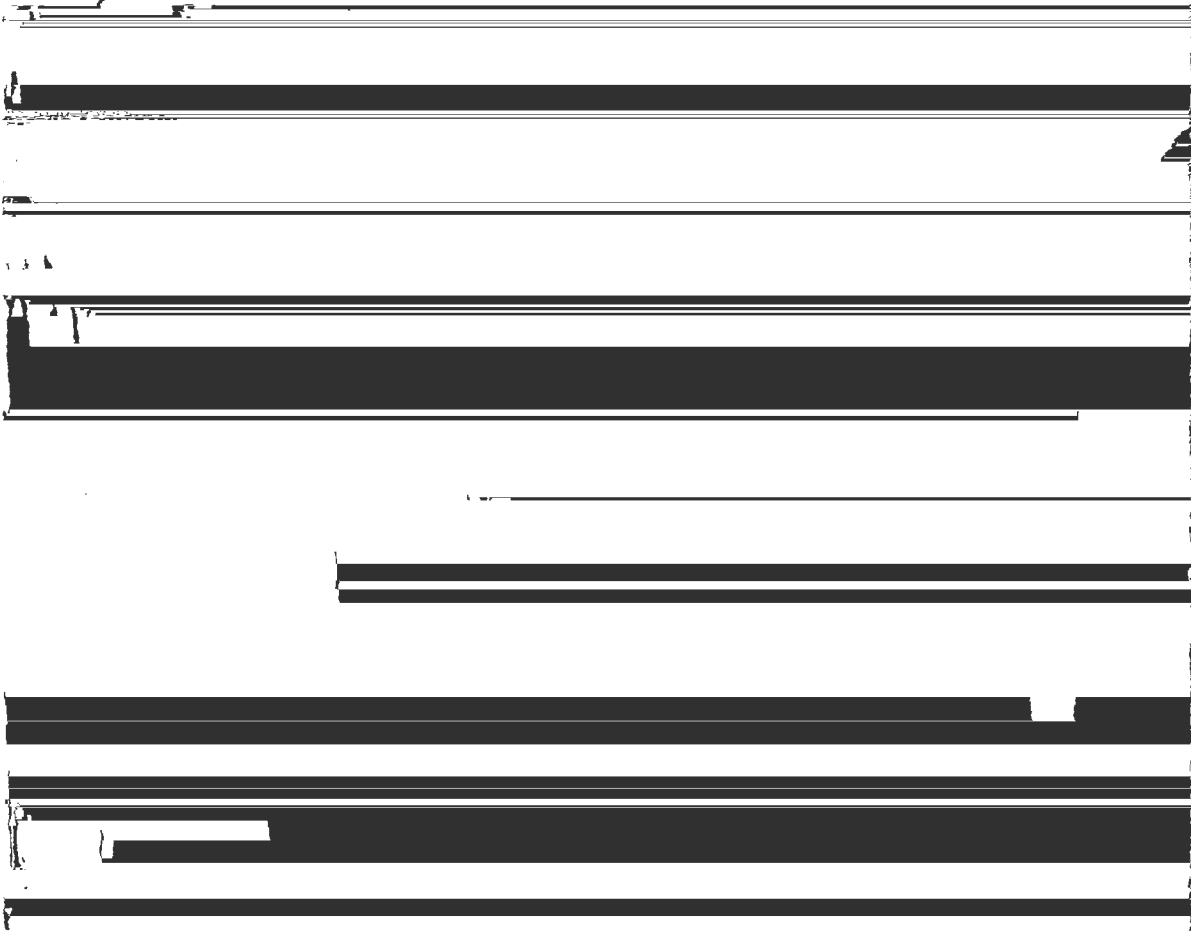
Test method for corrosion resistance (Annex A)

Method for determining peak tensile force (Annex B)

Test Method for Burst Pressure (Annex F)



Test for burst pressure under static conditions (Annex F)





A2LA has accredited

*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 14<sup>th</sup> 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.*