



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

MEDICAL DEVICE TESTING SERVICES
5929 Baker Road, Suite 430
Minnetonka, MN 55345
Peggy Wittenberg Phone: 952-933-1152 x21

MECHANICAL

Valid To: May 31, 2017

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 F2477-07; ISO 25539-1-Amendment 1; ISO 7198:1998
In-Vitro Curved Pulsatile Durability Testing of Vascular Stents	ASTM F2477-07; ISO 25539-1-Amendment 1; ISO 7198:1998
In-Vitro Simulated Gait Motion for Intravascular Devices	WI 99134 ¹
In-Vitro Simulated Tension/Compression for Intravascular Devices	WI 99134 ¹
In-Vitro Axial, Bending, Torsion Durability Testing of Vascular Stents	ASTM F2942-13
In-Vitro Simulated Bending for Intravascular Devices	WI 99134 ¹
<i>Medical Device Mechanical Testing:</i>	
Determination of Circumferential Tensile Strength	ISO 7198:1998, 8.3.1; ISO 25539-1-Amendment 1, D.5.3.8
Determination of Longitudinal Strength	ISO 7198:1998, 8.3.2; ISO 25539-1-Amendment 1, D.5.3.12
Determination of Kink Diameter/Radius	ISO 7198:1998, 8.9

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Test

Test Method(s)

Medical Device Mechanical Testing (cont'd):

Determination of Dynamic Compliance	ISO 7198:1998, 8.10
Crush Resistance	ISO 25539-1-Amendment 1, D.5.3.9
Migration Resistance	ISO 25539-1-Amendment 1, D.5.3.13
Pull Test for Modular Components	ISO 25539-1-Amendment 1, D.5.3.14
Strength of Stent Attachment to System to Graft	ISO 25539-1-Amendment 1, D.5.3.17
Compression	ISO 25539-1-Amendment 1, D.5.3.11
Hi Speed Video (Visual Evaluation)	WI 99134 ¹
Endoscopic Evaluation (<i>Visual Only</i>)	WI 99134 ¹

¹ In-house test method.





Accredited Laboratory

A2LA has accredited

MEDICAL DEVICE TESTING SERVICES

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 11th day of June 2015.

A handwritten signature in black ink, reading "Peter Abney".

President & CEO
For the Accreditation Council
Certificate Number 2783.01
Valid to May 31, 2017

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