SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

VIVITRO LABS SASU
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MECHANICAL

Valid To: January 31, 2027 Certificate Number: 3224.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following types of tests on medical products:

Test:	**Test Item(s)**	**Test Method(s):**
Acute Particulate Matter Generation: Number and size of fine particles (2 to 70) micrometers under steady or constant Flow (63 to 77) ml/min Temperature (35 to 39) °C	Endovascular Devices	ISO 25539-2 ASTM F2743 AAMI TIR42 FDA guidance 1545 FDA guidance 1608 OLE1032
Hydrodynamic Valve Performance Pulsatile Flow: Systemic pressure (up to +250 mmHg), Upstream pressure / Downstream pressure (-100 to +250) mmHg, Loss of transvalvular charge, Transvalvular flow (up to 50 l/min), Ejection volume (up to 180 ml), Regurgitant volume (closing volume + leakage volume), Pressures (-100 to +250) mmHg, flow rate (up to 50 l/min), and pulsation (3 to 200) BPM in physiological ranges EOA Temperature (20 to 45) °C	Cardiac Valve Prostheses and Cardiac Valve Repair Devices	ISO 5840-1, -2, -3 ISO 5910 OLE1714
Durability (AWT) Testing: Upstream pressure / Downstream pressure (-200 to +300) mmHg, Differential pressure Temperature (20 to 45) °C Fluid viscosity (1 to 4) cP Frequency (5 to 30) Hz Cycle counting % of passing cycles % of cycle above target differential pressure	Cardiac Valve Prostheses and Cardiac Valve Repair Devices	ISO 5840-1, -2, -3 ISO 5910 OLE2307

Test:	**Test Item(s)**	**Test Method(s):**
Pushability-Trackability-Withdrawability Testing Ratio of distal force to proximal force in pushability Pushability (Up to 1 Kg) Force to advance in Trackability (Up to 1 Kg) Force to withdraw in Withdrawability (Up to 1 Kg) Displacement (0.5 to 300) cm Temperature (20 to 45) °C	Endovascular Devices	ISO 25539-2 FDA Guidance 16007 OLE0811 OLE0813
Integral Water Leakage Rate of water leakage through the entire vascular implant (Up to 5 l/min) Pressure (0 up to 1000 mmHg) Dimension (Length up to 60 cm and Diameter up to 60 mm) Temperature (20 to 45) °C	Endovascular & Vascular Devices	ISO 7198 ISO 25539-1 OLE1215
Water Entry Pressure Visual leakage (detection at a specific pressure) Pressure (0 up to 1000 mmHg) Dimension (Length up to 60 cm and Diameter up to 60 mm) Temperature (20 to 45) °C	Endovascular & Vascular Devices	ISO 7198 OLE1512
Water Permeability Rate of water leakage through a unit area of vascular implant (Up to 5 l/min) Pressure (0 up to 1000 mmHg) Temperature (20 to 45) °C	Endovascular & Vascular Devices	ISO 7198 OLE1513
Flex Kink Evaluation of kink radius using a cone mandrel (4 to 40)mm Lab temperature	Endovascular Devices	ISO 25539-2 FDA Guidance 1608 FDA Guidance 16007 FDA Guidance 1545 OLE0810
Torqueability Evaluation of the transmission of rotation between proximal and distal extremities Temperature (20 to 45) °C	Endovascular Devices	FDA Guidance 16007 OLE0812
Dimensional Inspection Medical device or mechanical piece inspection or measurement Lab temperature	Endovascular & Vascular Devices	OLE1209
Fracture of Guidewires Evaluation of guidewires fracture using a cylindrical former Lab temperature	0.014” guidewire	ISO 11070 OLE2209
Resistance of guidewires to damage by flexing Evaluation of guidewires resistance to damage when flexing Lab temperature	0.014” guidewire	ISO 11070 OLE2210

Parameter	**Range:**
Flexible Scopes for measuring particles in fluids:	
Average Flow Rate	(63 to 77) ml/min
Particle Size	(2 to 70) µm
Particle Concentration	Up to 10 000 particles/ml
Temperature	(20 to 39) °C
Flexible Scopes for fluid testing:	
Pressure	(-200/+1000) mmHg
Average Flow Rate	(0 to 30) l/min
Temperature	(20 to 45) °C
Frequency	(5 to 30) Hz
Fluid viscosity	(1 to 4) Cp
Flexible Scopes for force testing:	
Force	(0 to 1) kg

[1] This scope meets A2LA's *P112 Flexible Scope Policy*

Accredited Laboratory

A2LA has accredited

VIVITRO LABS SASU

Marseille, France

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 31st day of January 2025.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3224.02
Valid to January 31, 2027

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