



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

VIVITRO LABS SASU  
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MECHANICAL

Valid To: January 31, 2025

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 tests on medical products:

<u>Test:</u>	<u>Test Method(s):</u>
<b><i>Endovascular Devices:</i></b>	
Number and size of fine particles (2-70 micrometers) under steady or constant Flow	ISO 25539-2; ASTM F2743
<b><i>Cardiac Valve Prostheses and Cardiac Valve Repair Devices:</i></b>	
Systemic pressure, Upstream pressure / Downstream pressure, Loss of transvalvular charge, Transvalvular flow, Ejection volume, Regurgitant volume (closing volume + leak volume), Pressures, flow rate and pulsation in physiological ranges	ISO 5840-1, -2, -3, ISO 5910

<u>Test:</u>	<u>Range:</u>	<u>Test Method(s):</u>
<b><i>Testing Parametric Envelope for measuring particles in fluids:</i></b>		
Average Flow Rate	(63 to 77) ml/min	OLE 1032
Particle Size	(2 to 70) $\mu\text{m}$	
Particle Concentration	Up to 10 000 particles/ml	
Temperature	(20 to 39) $^{\circ}\text{C}$	
<b><i>Testing Parametric Envelope for fluid testing:</i></b>		
Pressure	-50/+200 mmHg	OLE 1714
Average Flow Rate	(0 to 7) l/min	
Temperature	(20 to 45) $^{\circ}\text{C}$	
Frequency	(0 to 3.5) Hz	
Fluid viscosity	(1 to 10) Cp	





# 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 26<sup>th</sup> day of April 2023.

A blue ink signature of Mr. Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 3224.02  
Valid to January 31, 2025

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