

List Number

EU Declaration of Conformity

Basic UDI-DI:

038074DAL0005FW

Basic UDI-DI Name:

ARCHITECT Reaction Vessels

Risk Class:

Class A

Product and Trade Name

and Size Code	<u> </u>			
7C15-03	ARCHITECT Reacti	on Vessels	56676	W0201020185
	Manufacturer	Abbott Laboratories		
(Name and Address)				
	,	Irving, TX 75038 USA		
	Manufacturer SRN	US-MF-000017777		
Auth	horized Representative	Abbott GmbH		
	(Name and Address)	Max-Planck-Ring 2		
		65205 Wiesbaden, Germany		

DE-AR-000009457 **Authorized Representative SRN** Produced by (Site of Manufacture) Abbott Laboratories Abbott Park, Illinois 60064 USA

(Name and Address)

Conformity Assessment Procedure Annex II and III

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

Full Name:	Thomas Creel	Melissa Vaughan Full Name:	
run Name.	Sr. Director, Instrument and Automation		Director Regulatory Affairs
Function:	Quality	Function:	
Signature:	Chomes Cuel		Melina Vaythan
Date of Approval:	18-July-2025	Date of Approval:	18-July-2025
Signed for, and on behalf of:	Alobott Laboratories, 1915	Hurd Dr. Inv.	ing TX 75038 USA
	18-July-2025 02 Sep, 2022		Mobott Laboratories 1915 Hurd Drive, Irving, TX 75038
Supersedes:	02 Sep, 2022 /	Effective (Date or Lot Number):	

EMDN Code

GMDN Code