

## **EU Declaration of Conformity**

**Basic UDI-DI:** 

038074DAL0005FW

**Basic UDI-DI Name:** 

ARCHITECT Sample Cups

**Risk Class:** 

Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
7C14-01	ARCHITECT Sample Cups	56676	W0201020185

Manufacturer	Abbott Laboratories
(Name and Address)	1915 Hurd Drive
•	Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative	Abbott GmbH
(Name and Address)	Max-Planck-Ring 2
	65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture)	Abbott Laboratories
(Name and Address)	Abbott Park, Illinois 60064 USA
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.

Euli Namo	Thomas Creel	Full Name:	Melissa Vaughan
Full Name:	Sr. Director, Instrument and Automation		Director Regulatory Affairs
Function:	Quality	Function:	
Signature:	Thomas Cuel		Melina Vaughan
Date of Approval:	18- July -2025	Date of Approval:	18- July - 2025
Signed for, and on behalf of:	Abhott Laboratories, 1915	Hyrd Or 1	rving TX 75038 USA
	18-July-2025		Abbott Laboratories 1915 Hurd Drive, Irving, TX 75038
Supersedes:	16 Sep, 2022	Effective (Date or Lot Number):	18- July-2025