

List Number

EU Declaration of Conformity

Basic UDI-DI:

038074DAL0005FW

Basic UDI-DI Name:

ARCHITECT Sample Cups

Risk Class: Class A

> **GMDN** Code **EMDN** Code **Product and Trade Name**

and Size Code ARCHITECT Sample Cups 7C14-01 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) | NYPRO CHICAGO |
| (Name and Address) | 955 Tri-State Parkway |
| | Gurnee, IL 60031 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, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

| Full Name: | Thomas Creel | Full Name: | Amanda Peoples |
|--------------------|---|-------------------|-------------------------------------|
| | Sr. Director, Instrument and Automation | | |
| Function: | Quality | Function: | Project Manager, Regulatory Affairs |
| Signature: | Phoneys Creek | Signature: | Amenda Reoples |
| Date of Approval: | 14-50-2022 | Date of Approval: | 16- Sep- 2022 |
| Signed for, and on | | | , |
| behalf of: | | | |
| | Irving, TX 75038 | | |
| Date Issued: | 16-5ep-0022 | Place Issued: | Irving, Texas |
| | | Effective (Date | |
| Supersedes: | 24 May 2022 | or Lot Number): | 16-Sep- 2002 |
| | | Effective (Date | // / 2 222 |