



EU Declaration of Conformity

Basic UDI-DI: 038074DAL0005FW
Basic UDI-DI Name: ARCHITECT Septum
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
4D18-03	ARCHITECT Septum	56676	W0201020185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	MGS Germantown A Division of MGS Group NA Inc W190 N11701 Moldmakers Way Germantown, WI 53022 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
Sr. Director, Instrument and Automation

Function: Quality

Signature: Thomas Creel

Date of Approval: 31-Aug-2022

Signed for, and on behalf of: Abbott Laboratories
1915 Hurd Drive
Irving, TX 75038

Full Name: Michele Smith-Waheed

Function: Associate Director, Regulatory Affairs

Signature: M. Waheed

Date of Approval: 02-Sept-2022

Date Issued: 02-Sept-2022

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Place Issued: Irving, Texas

Effective (Date or Lot Number): 02-Sept-2022