Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074SLI0002T5
Basic UDI-DI Name: ARCHITECT System Solutions
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
7D82-50	ARCHITECT Multi-Assay Manual Diluent	58208	W0201020185
1L56-40	ARCHITECT Probe Conditioning Solution	59058	W0201020185
6C54-58	ARCHITECT Concentrated Wash Buffer	58236	W0201020185
6C54-82	ARCHITECT Concentrated Wash Buffer	58236	W0201020185
6C54-88	ARCHITECT ARM Concentrated Wash Buffer	58236	W0201020185
6C55-60	ARCHITECT Trigger Solution	58793	W0201020185
6C55-82	ARCHITECT Trigger Solution	58793	W0201020185
6E23-65	ARCHITECT Pre-Trigger Solution	61163	W0201020185
6E23-82	ARCHITECT Pre-Trigger Solution	61163	W0201020185

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
Manufacturer SRN	IE-MF-000009849
Authorized Representative (Name and Address)	N/A
Authorized Representative SRN	N/A
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
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. **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: Noel Haren
Function: Manager Regulatory Affairs
Signature:
Date of Approval: 23 May 2022

Full Name: Joe Murray
Function: Director Quality Assurance
Signature:
Date of Approval: 23 May 2022

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Sligo

Date Issued: 23 May 2022
Supersedes: N/A

Place Issued: Sligo, Ireland
Effective (Date or Lot Number): 23 May 2022

Digitally signed by Ceaicovschi Tudor
Date: 2024.06.25 16:42:45 EEST
Reason: MoldSign Signature
Location: Moldova