

Declaration of Conformity


Certificate Identification: DoC-6C55-63, 6E23-68-AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland


List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C55-63	58793	ARCHITECT Trigger Solution	Self-declared
6E23-68	61163	ARCHITECT Pre-Trigger Solution	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland Department: Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 
 Full Name: Joe Murray
 Position: Director Quality Assurance/Site Quality Head
 Date of Approval: 28 Sep 2020
 Date Issued: 29 Sep 2020
 Supersedes: N/A

Signature: 
 Full Name: Noel Haren
 Position: Manager Regulatory Affairs
 Date of Approval: 29 Sep 2020
 Place Issued: AIDD Sligo
 Effective (Date or Lot Number): 29 Sep 2020