

Declaration of Conformity


Certificate Identification:
Legal Manufacturer's Name:
Legal Manufacturer's Address:

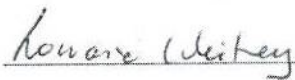
ARCHITECT Solutions
Abbott Ireland Diagnostics Division
Finisklin Business Park
Sligo
Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1L56-40	59058	ARCHITECT Probe Conditioning Solution	Self-declared
6C54-58	58236	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-82	58236	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-88	58236	ARCHITECT ARM Concentrated Wash Buffer	Self-declared
6C55-60	58793	ARCHITECT Trigger Solution	Self-declared
6C55-82	58793	ARCHITECT Trigger Solution	Self-declared
6E23-65	61163	ARCHITECT Pre-Trigger Solution	Self-declared
6E23-82	61163	ARCHITECT Pre-Trigger Solution	Self-declared
7D82-50	58208	ARCHITECT Multi-Assay Manual Diluent	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, County 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: Niall Plunkett
Position: Quality Manager
Date of Approval: 16 Oct 14
Date Issued: 16 Oct 14
Supersedes: 07 July 2014

Signature: 
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 14 Oct 2014
Place Issued: AIDD Sligo
Effective (Date or Lot Number): 16 Oct 14