Abbott

Declaration of Conformity

Certificate Identification:	DoC-08P10-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
08P1022	48321	Alinity i HBsAg Qualitative II Reagent Kit	**Annex II List A**
08P1032	48321	Alinity i HBsAg Qualitative II Reagent Kit	**Annex II List A**
08P1001	41999	Alinity i HBsAg Qualitative II Calibrators	**Annex II List A**
08P1010	42000	Alinity i HBsAg Qualitative II Controls	**Annex II List A**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body number	0123
Approval Certificate No.	V7 0019220015
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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Joe Murray	Signature:	Noel Haren
Full Name:	Joe Murray	Full Name:	Noel Haren
Position:	Director Quality Assurance/Site Quality Head	Position:	Manager Regulatory Affairs
Date of Approval:	17 Jun 2021	Date of Approval:	17 Jun 2021
Date Issued:	17 Jun 2021	Place Issued:	AIDD, Sligo
Supersedes:	12 Oct 2020	Effective (Date or Lot Number):	17 Jun 2021