

Declaration of Conformity

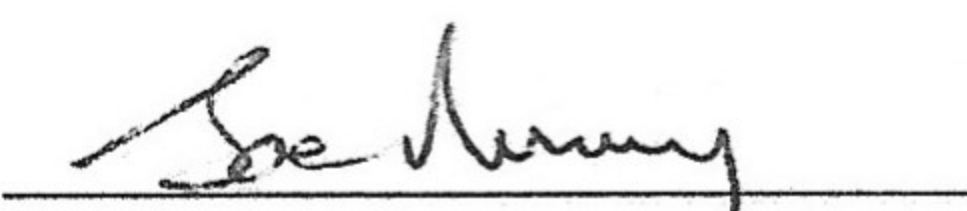
Certificate Identification: DoC-08P10-AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland


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: 
 Full Name: Joe Murray
 Position: Director Quality Assurance/Site Quality Head

Signature: 
 Full Name: Noel Haren
 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