

Declaration of Conformity

Certificate Identification:

DoC-2G22-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
2G22-25	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-30	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-35	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-01	41999	ARCHITECT HBsAg Qualitative II Calibrators	Annex II List A
2G22-10	42000	ARCHITECT HBsAg Qualitative II Controls	Annex II List A

Authorized European	N/A
Representative (name and address)	
Notified Body (name and address)	TÜV SÜD Product Service GmbH
	Ridlerstraße 65
	80339 Munich
	Germany
Notified Body number	0123
Approval Certificate No.	V7 0019220009
Storage site of technical	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland.
documentation (name and address)	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:

Ice Murroy

Signature:

Car or

Full Name:

Joe Murray

Full Name:

Noel Haren

Position:

Director Quality Assurance/Site Quality Head

Position:

Manager Regulatory Affairs

Date of Approval:

27 001 2020

Date of Approval:

27 DET 2000

Date Issued:

27 OCT 2020

Place Issued:

AIDD, Sligo

Supersedes:

25 November 2019

Effective (Date or Lot Number):

27 OCT 2020