

# 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

<b>Authorized European Representative (name and address)</b>	N/A
<b>Notified Body (name and address)</b>	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
<b>Notified Body number</b>	0123
<b>Approval Certificate No.</b>	V1 0019220008
<b>Storage site of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland. Department: Regulatory Affairs.
<b>Harmonized Standards</b>	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: <sup>x</sup> **N. WALSH** *N Walsh*  
 Full Name: <sup>x</sup> Joe Murray  
 Position: Director Quality Assurance/Site Quality Head  
 Date of Approval: 25 Nov 2019  
 Date Issued: 25 Nov 2019  
 Supersedes: 16 October 2019

Signature: *Noel Haren*  
 Full Name: Noel Haren  
 Position: Manager Regulatory Affairs  
 Date of Approval: 25 Nov 2019  
 Place Issued: AIDD, Sligo  
 Effective (Date or Lot Number): 25 Nov 2019

*x Ref attached delegation memo Walsh 25 Nov 2019*