

Declaration of Conformity

Certificate Identification:	<u>04U30</u>
Legal Manufacturer's Name:	<u>Abbott Ireland Diagnostics Division</u>
Legal Manufacturer's Address:	<u>Lisnamuck, Longford, Co. Longford, Ireland.</u>

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04U3020	53599	Albumin BCG2	Self-declared
04U3030	53599	Albumin BCG2	Self-declared

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
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: *Siobhan Wright*
 Full Name (printed): **Siobhan Wright**
 Position: **Director Quality Assurance/
Site Quality Head**

Signature: *Lorraine Whitney*
 Full Name (printed): **Lorraine Whitney**
 Position: **Director Regulatory Affairs**

Date of Approval: 25 OCT - 20

Date of Approval: 25 OCT 2020

Date Issued: 25 OCT - 20

Place Issued: **Abbott Ireland Diagnostics Division,
Lisnamuck, Longford, Co. Longford, Ireland.**

Supersedes: N/A

Effective (Date or Lot Number): 25 OCT - 20