

Declaration of Conformity

Certificate Identification: 04T85
 Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
 Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

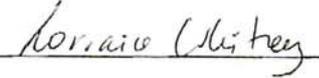
| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---------------------------------------|-----------|----------------------------------|----------------|
| 04T8520 | 52941 | Amylase2 | Self-declared |

| | |
|---|--|
| Authorized European Representative (name and address) | Not Applicable |
| 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: 
 Full Name (printed): **Siobhan Wright**
 Position: **Director Quality Assurance/
 Site Quality Head**

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

Date of Approval: 25-05-20

Date of Approval: 25 OCT 2020

Date Issued: 25-05-20

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

Supersedes: Not Applicable

Effective Date: 25-05-20