

Declaration of Conformity

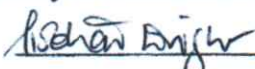
Certificate Identification: 07P69
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

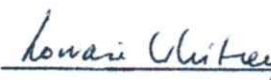
| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---------------------------------------|-----------|----------------------------------|----------------|
| 07P6920 07P6930 | 54417 | Alinity i Free T3 Reagent Kit | Self-declared |
| 07P6901 | 38261 | Alinity i Free T3 Calibrators | Self-declared |
| 07P6910 | 54418 | Alinity i Free T3 Controls | 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: 
Full Name: Siobhan Wright
Position: Director Quality Assurance/
Site Quality Head
Date of Approval: 01-MAY-2020
Date Issued: 01-MAY-2020
Supersedes: 24 April 2019 _____

Signature: 
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 01 MAY 2020
Place Issued: Abbott Ireland Diagnostics Division,
Lisnamuck, Longford, Co. Longford,
Ireland
Effective (Date or Lot Number): 01-MAY-2020