

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