

Declaration of Conformity

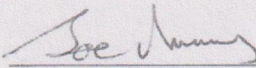
Certificate Identification: DoC_09P35_AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

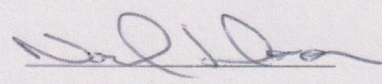
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09P3522	58729	Alinity i Anti-TPO Reagent Kit	Self-declared
09P3501	55210	Alinity i Anti-TPO Calibrators	Self-declared
09P3510	55211	Alinity i Anti-TPO Controls	Self-declared

Authorized European Representative (name and address)	NA
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland and Fisher Diagnostics, A Div. of Fisher Scientific Company, LLC A Part of Thermo Fisher Scientific, Inc. 8365 Valley Pike, Middletown VA 22645 USA
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: **Joe Murray**
 Position: **Director Quality Assurance/ Site Quality Manager**

Signature: 
 Full Name: **Noel Haren**
 Position: **Manager Regulatory Affairs**

Date of Approval: 22 May 2020

Date of Approval: 25 May 2020

Date Issued: 25 May 2020

Place Issued: AIDD, Sligo

Supersedes: 09 Nov 2017

Not applicable

Effective (Date or Lot Number): 25 May 2020