Abbott

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:	Joe Murray	Signature:	Noel Haren
Full Name:	**Joe Murray**	Full Name:	**Noel Haren**
Position:	**Director Quality Assurance/ Site Quality Manager**	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