Abbott

Declaration of Conformity

Certificate Identification: DOC-07P51-AIDD Longford
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
07P5120	54215	Alinity i Total β-hCG Reagent Kit	**Self-declared**
07P5130	54215	Alinity i Total β-hCG Reagent Kit	**Self-declared**
07P5101	38266	Alinity i Total β-hCG Calibrators	**Self-declared**
07P5110	38265	Alinity i Total β-hCG Controls	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland Department: Regulatory Affairs
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:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name:	Siobhan Wright	Full Name:	Lorraine Whitney
Position:	Director Quality Assurance/ Site Quality Head	Position:	Senior Manager Regulatory Affairs
Date of Approval:	24-APR-19	Date of Approval:	19 APR 2019
Date Issued:	24-APR-19	Place Issued:	AIDD Longford
Supersedes:	16-Feb-2017	Effective (Date or Lot Number):	24-APR-19