Abbott

Declaration of Conformity

Certificate Identification: DOC-07P66-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
07P6620	54335	Alinity i Prolactin Reagent Kit	**Self-declared**
07P6630	54335	Alinity i Prolactin Reagent Kit	**Self-declared**
07P6601	54337	Alinity i Prolactin Calibrators	**Self-declared**
07P6610	54338	Alinity i Prolactin 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:	31-DEC-16	Effective (Date or Lot Number):	24-APR-19