Abbott

Declaration of Conformity

Certificate Identification: 08P36
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
08P3620 08P3630	54322	Alinity i Progesterone Reagent Kit	**Self-declared**
08P3601	54325	Alinity i Progesterone Calibrators	**Self-declared**
08P3610	54326	Alinity i Progesterone Controls	**Self-declared**
08P3640	58208	Alinity i Progesterone Manual Diluent	**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: Siobhan Wright
Full Name: Siobhan Wright
Position: Director Quality Assurance / Site Quality Head
Date of Approval: 24-APR-19
Date Issued: 24-APR-19
Supersedes: 21-Dec-2017

Signature: Lorraine Whitney
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 19 APR 2019
Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 24-APR-19