Abbott

Declaration of Conformity

Certificate Identification: 08P14/08P15
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
08P1422 08P1432	60982	Alinity i Folate Reagent Kit	**Self-declared**
08P1440	54455	Alinity i Folate RBC Lysis Diluent	**Self-declared**
08P1460	58208	Alinity i Folate Manual Diluent	**Self-declared**
08P1401	41931	Alinity i Folate Calibrators	**Self-declared**
08P1410	41932	Alinity i Folate Controls	**Self-declared**
08P1542	54455	Alinity i Folate Lysis Reagent	**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	Signature:	Lorraine Whitney
Full Name:	Siobhan Wright	Full Name:	Lorraine Whitney
Position:	DirectorQuality 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:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	07 Feb 18	Effective (Date or Lot Number):	24-APR-19