

Declaration of Conformity

Certificate Identification: 07P91
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
07P9120 07P9130	54254	Alinity i LH Reagent Kit	Self-declared
07P9101	38270	Alinity i LH Calibrators	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: 

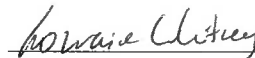
Full Name: Siobhan Wright

Position: Director Quality Assurance//Site Quality Head

Date of Approval: 24 - APR - 19

Date Issued: 24 - APR - 19

Supersedes: 15-Dec-17

Signature: 

Full Name: Lorraine Whitney

Position: Senior Manager Regulatory Affairs

Date of Approval: 12 APR 2019

Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland

Effective (Date or Lot Number): 24 - APR - 19