

Declaration of Conformity

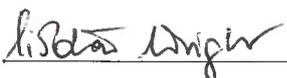
Certificate Identification: DOC-07P65-AIDD Longford
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
07P6520	61078	Alinity i Ferritin Reagent Kit	Self-declared
07P6530	61078	Alinity i Ferritin Reagent Kit	Self-declared
07P6501	41927	Alinity i Ferritin Calibrators	Self-declared
07P6510	41928	Alinity i Ferritin 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: 

Signature: 

Full Name: Siobhan Wright _____

Full Name: Lorraine Whitney _____

Position: Director Quality Assurance / Site Quality Head

Position: Senior Manager Regulatory Affairs

Date of Approval: 17-DEC-18

Date of Approval: 17 DEC 18

Date Issued: 17 Dec 2018

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

Supersedes: 31 Dec 2016

Effective (Date or Lot Number): 17 DEC 18