Abbott

Declaration of Conformity

Certificate Identification: DOC-07P90-AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
07P9020	58348	Alinity i AFP Reagent Kit	**Self-declared**
07P9030	58348	Alinity i AFP Reagent Kit	**Self-declared**
07P9010	54063	Alinity i AFP Controls	**Self-declared**
07P9001	54062	Alinity i AFP Calibrators	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, 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:	Joe Murray	Full Name:	Noel Haren
Position:	Director Quality Assurance/Site Quality Head	Position:	Manager Regulatory Affairs
Date of Approval:	27 Sep 19	Date of Approval:	26 Sept 2019
Date Issued:	27 SEP 2019	Place Issued:	AIDD, Sligo
Supersedes:	27 Nov 2017	Effective (Date or Lot Number):	27 SEP 2019