

Declaration of Conformity

Certificate Identification: DoC-06P1368-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
06P1368	58236	Alinity i-series Concentrated Wash Buffer	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: _____
Full Name:

Position:

Date of Approval: 03 Jan 17

Date Issued: 03 Jan 17

Supersedes: 31 Dec 16

Signature: _____
Full Name:

Position:

Date of Approval: 03 Jan 17

Place Issued: AIDD, Sligo

Effective (Date or Lot Number): 03 Jan 17