

## Declaration of Conformity

**Certificate Identification:** DoC-09P1540-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
09P1540	58208	Alinity i Multi-Assay Manual Diluent	Self-declared

<b>Authorized European Representative (name and address)</b>	N/A
<b>Storage site of technical documentation (name and address)</b>	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland Department: Regulatory Affairs
<b>Harmonized Standards</b>	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:

Signature: \_\_\_\_\_  
Full Name:

Position:

Position:

Date of Approval: 03 Jan 17

Date of Approval: 03 Jan 17

Date Issued: 03 Jan 17

Place Issued: AIDD, Sligo

Supersedes: 31 Dec 16

Effective (Date or Lot Number): 03 Jan 17