Abbott

# Declaration of Conformity

**Certificate Identification:** DOC-07P62-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 |
|---|---|---|---|
| 07P6220 | 54615 | Alinity i CEA Reagent Kit | **Self-declared** |
| 07P6230 | 54615 | Alinity i CEA Reagent Kit | **Self-declared** |
| 07P6210 | 38173 | Alinity i CEA Controls | **Self-declared** |
| 07P6201 | 38174 | Alinity i CEA 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<br>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.**

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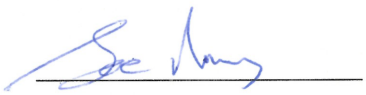
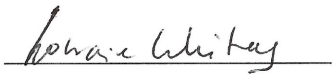
|---|---|---|---|
| Signature: |  | Signature: |  |
| Full Name: | Joe Murray | Full Name: | Lorraine Whitney |
| Position: | Quality Manager | Position: | Senior Manager Regulatory Affairs |
| Date of Approval: | 30 Apr 18 | Date of Approval: | 27 April 2018 |
| Date Issued: | 30 Apr 18 | Place Issued: | AIDD, Sligo |
| Supersedes: | 11 Jan 2017 | Effective (Date or Lot Number): | 30 Apr 18 |