

Declaration of Conformity

Certificate Identification: DOC-07P48-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 |
|---------------------------------------|-----------|----------------------------------|----------------|
| 07P4820 | 54386 | Alinity i TSH Reagent Kit | Self-declared |
| 07P4830 | 54386 | Alinity i TSH Reagent Kit | Self-declared |
| 07P4801 | 38272 | Alinity i TSH Calibrators | Self-declared |
| 07P4810 | 38271 | Alinity i TSH Controls | Self-declared |

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| 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.

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|------------------|------------------------------|
| Signature: _____ | Signature: <u>J</u> _____ |
| Full Name: _____ | Full Name: _____ |
| Position: _____ | Position: Regulatory Affairs |

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| Date of Approval: <u>02-MAY-18</u> | Date of Approval: <u>01 May 2018</u> |
| Date Issued: <u>02-MAY-18</u> | Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland |
| Supersedes: 31 December 2016 | Effective (Date or Lot Number): <u>02-MAY-18</u> |