

Declaration of Conformity

Certificate Identification: DOC-08P13-AIDD Longford
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
 Lisnamuck, Longford,
 Co. Longford
Legal Manufacturer's Address: Ireland

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|--|-----------|--|----------------|
| 08P1322 08P1324 08P1327 08P1332 08P1334 08P1337 | 60780 | Alinity i STAT High Sensitive Troponin-I Reagent Kit | Self-declared |
| 08P1301 | 54011 | Alinity i STAT High Sensitive Troponin-I Calibrators | Self-declared |
| 08P1310 | 54012 | Alinity i STAT High Sensitive Troponin-I 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.

Signature: Siobhan Wright

Full Name: Siobhan Wright

Position: Director Quality Assurance

Date of Approval: 20-APR-2021

Date Issued: 20-APR-2021

Supersedes: 17 Dec 20

Signature: Thomas Breslin

Full Name: Thomas Breslin

Position: Manager Regulatory Affairs

Date of Approval: 20 APRIL 2021

Place Issued: Abbott Ireland Diagnostics Division,
Lisnamuck, Longford, Co. Longford,
Ireland

Effective (Date or Lot Number): 20-APR-2021