Abbott

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**

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:

Full Name:

Position:

Date of Approval: 17-Dec-2020

Date Issued: 17-Dec-2020

Supersedes: 23 Jan 2019

Signature:

Full Name:

Position:

Date of Approval: 16 Dec 2020

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

Effective (Date or Lot Number): 17-Dec-2020