Abbott

Declaration of Conformity

Certificate Identification: DoC-08P06 -AII DELK
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08P0622	48366	Alinity i Anti-HCV Reagent Kit (2 x 100 Tests)	**Annex II List A**
08P0632	48366	Alinity i Anti-HCV Reagent Kit (2 x 500 Tests)	**Annex II List A**
08P0601	41972	Alinity i Anti-HCV Calibrator	**Annex II List A**
08P0610	41973	Alinity i Anti-HCV Controls	**Annex II List A**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom
Notified Body number	**0088**
Approval Certificate No.	**0088/0964174/00188**
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, Max-Planck-Ring 2, 65205 Wiesbaden, Germany.
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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:

Full Name:

Position:

Date of Approval: 2018-12-06

Signature:

Full Name:

Position:

Date of Approval: 04/Dec/2018

Date Issued: 06/Dec/2018

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 31-Dec-2016

Effective (Date or Lot Number): 08P0622: #95571LI00