Abbott

Declaration of Conformity

Certificate Identification: DOC-6C37-22/-27/-32/-37-AII DLK

Legal Manufacturer's Name: Abbott GmbH

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
6C37-22	48366	ARCHITECT Anti-HCV Reagent Kit (4x100Tests)	**Annex II List A**
6C37-27	48366	ARCHITECT Anti-HCV Reagent Kit (1x100Tests)	**Annex II List A**
6C37-32	48366	ARCHITECT Anti-HCV Reagent Kit (4x500 Tests)	**Annex II List A**
6C37-37	48366	ARCHITECT Anti-HCV Reagent Kit (1x500 Tests)	**Annex II List A**
6C37-01	41972	ARCHITECT Anti-HCV Calibrator	**Annex II List A**
6C37-10	41973	ARCHITECT Anti-HCV Controls	**Annex II List A**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
Notified Body number	TÜV SÜD: 0123
Approval Certificate No.	TÜV SÜD: V7 010051 0132
Storage site of technical documentation (name and address)	Abbott GmbH, 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: **Dr. Jörg Amborn**

Position: **Director Quality Assurance**

Date of Approval: 2020-02-09

Digitally signed by Ceaicovschi Tudor
Date: 2021.02.09 08:37:44 EET
Reason: MoldSign Signature
Location: Moldova

Signature:

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 04/FEB/2020

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Place Issued: 65205 Wiesbaden, Germany

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