Abbott

Declaration of Conformity

Certificate Identification: DoC 8D06-SD DELK
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
8D06-32	59861	ARCHITECT Syphilis TP Reagent Kit (1x100 Tests)	**Self-declared**
8D06-42	59861	ARCHITECT Syphilis TP Reagent Kit (1x500 Tests)	**Self-declared**
8D06-04	51802	ARCHITECT Syphilis TP Calibrator	**Self-declared**
8D06-13	37733	ARCHITECT Syphilis TP Controls	**Self-declared**

Authorized European Representative (name and address)	N/A
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 III 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: 2020-09-09

Digitally signed by Ceaicovschi Tudor
Date: 2021.02.08 16:26:42 EET
Reason: MoldSign Signature
Location: Moldova

Signature: _____
Full Name: **Susanne Ulrich**
Position: **Senior Manager Regulatory Affairs**
Date of Approval: 08/Sep/2020
Date Issued: 10/Sep/2020
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 09-Mar-2020
Effective (Date or Lot Number): 10/Sep/2020