

## 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) | <b>Self-declared</b> |
| 8D06-42                               | 59861     | ARCHITECT Syphilis TP Reagent Kit (1x500 Tests) | <b>Self-declared</b> |
| 8D06-04                               | 51802     | ARCHITECT Syphilis TP Calibrator                | <b>Self-declared</b> |
| 8D06-13                               | 37733     | ARCHITECT Syphilis TP Controls                  | <b>Self-declared</b> |

|   |  |
|---|--|
| <b>Authorized European Representative (name and address)</b>      | N/A  |
| <b>Storage site of technical documentation (name and address)</b> | Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany |
| <b>Harmonized Standards</b>                                       | 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.

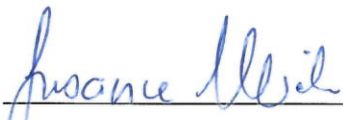
**This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

Signature: 

Full Name: **Dr. Jörg Amborn**

Position: **Director Quality Assurance**

Date of Approval: 2020-09-09

Signature: 

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 03/Sep/2020

Date Issued: 10/Sep/2020

Place Issued: 65205 Wiesbaden, Germany

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