Abbott

Declaration of Conformity

Certificate Identification: DoC-08P07 -AII 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
08P0722	48446	Alinity i HIV Ag/Ab Combo Reagent Kit (2 x 100 Tests)	**Annex II List A**
08P0732	48446	Alinity i HIV Ag/Ab Combo Reagent Kit (2 x 600 Tests)	**Annex II List A**
08P0701	48448	Alinity i HIV Ag/Ab Combo Calibrator	**Annex II List A**
08P0710	48449	Alinity i HIV Ag/Ab Combo 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 0113
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: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 06 May 2021

Signature: Susanne Ulrich
Full Name: **Susanne Ulrich**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 04/May/2021
Date Issued: 06-May-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 01-April-2020
Effective (Date or Lot Number): 06-May-2021