Declaration of Conformity

Certificate Identification:		DOC-4J27-AII DLK
Legal Manufacturer's Name:		Abbott GmbH
Legal Manufacturer's Address:		Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Codes of Devices	GMDN Code	Names and Description of Devices	Classification
4J27-22	48446	ARCHITECT HIV Ag/Ab Combo Reagent Kit (4x100 Tests)	Annex II List A
4J27-27	48446	ARCHITECT HIV Ag/Ab Combo Reagent Kit (1x100 Tests)	Annex II List A
4J27-32	48446	ARCHITECT HIV Ag/Ab Combo Reagent Kit (4x500 Tests)	Annex II List A
4J27-37	48446	ARCHITECT HIV Ag/Ab Combo Reagent Kit (1x500 Tests)	Annex II List A
4J27-03	48448	ARCHITECT HIV Ag/Ab Combo Calibrator	Annex II List A
4J27-12	48449	ARCHITECT 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 0118
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*	Signature:	*Susanne Ulrich*
Full Name:	**Claudia Becker**	Full Name:	**Susanne Ulrich**
Position:	**Director Quality Assurance**	Position:	**Assoc. Director Regulatory Affairs**
Date of Approval:	06 May 2021	Date of Approval:	04/ May / 2021
Date Issued:	06-May-2021	Place Issued:	65205 Wiesbaden, Germany
Supersedes:	10-Mar-2020	Effective (Date or Lot Number):	06- May - 2021