

Declaration of Conformity


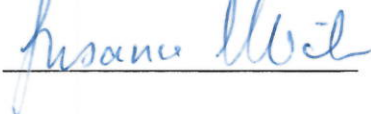
Certificate Identification: DoC 8L44 AII DELK
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
8L44-25	48304	ARCHITECT Anti-HBc II Reagent Kit (1x100 Tests)	Annex II List A
8L44-30	48304	ARCHITECT Anti-HBc II Reagent Kit (4x500 Tests)	Annex II List A
8L44-35	48304	ARCHITECT Anti-HBc II Reagent Kit (1x500 Tests)	Annex II List A
8L44-01	41983	ARCHITECT Anti-HBc II Calibrator	Annex II List A
8L44-10	41984	ARCHITECT Anti-HBc II 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 0130
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, 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: <u></u> Full Name: Dr. Jörg Amborn Position: Director Quality Assurance Date of Approval: <u>2019-10-21</u>	Signature: <u></u> Full Name: Susanne Ulrich Position: Senior Manager Regulatory Affairs Date of Approval: <u>16/10/2019</u> Date Issued: <u>21/10/2019</u> Place Issued: 65205 Wiesbaden, Germany Supersedes: 30-03-2019 Effective (Date or Lot Number): 8L44-01: 10201BE00 8L44-10: 09522BE00 8L44-25: 09537BE00 8L44-30: 09542BE00 8L44-35: 09559BE00
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