Abbott

Declaration of Conformity

Certificate Identification: DoC-08P49-SD DELK TPM
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
08P4920	54588	Alinity i CA 125 II Reagent Kit (2 x 100 Tests)	**Self-declared**
08P4930	54588	Alinity i CA 125 II Reagent Kit (2 x 500 Tests)	**Self-declared**
08P4901	38231	Alinity i CA 125 II Calibrators	**Self-declared**
08P4910	38230	Alinity i CA 125 II Controls	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, Pennsylvania 19355, USA.
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.

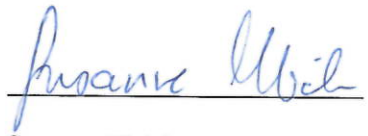
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 

Full Name: **Dr. Jörg Amborn**

Position: **Director Quality Assurance**

Date of Approval: 2020-05-14

Signature: 

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 12/May/2020

Date Issued: 14-May-2020

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 29-Mar-2017

Effective (Date or Lot Number): 14-May-2020