

Declaration of Conformity

Certificate Identification: DoC-08P51-SD DLK 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
08P5120	60975	Alinity i CA 15-3 Reagent Kit (2 x 100 Tests)	Self-declared
08P5130	60975	Alinity i CA 15-3 Reagent Kit (2 x 500 Tests)	Self-declared
08P5101	38223	Alinity i CA 15-3 Calibrators	Self-declared
08P5110	38222	Alinity i CA 15-3 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:

Claudia Becker

Position:

Director Quality Assurance

Date of Approval:

20 Dec 2021

Signature:



Full Name:

Susanne Ulrich

Position:

Assoc. Director Regulatory Affairs

Date of Approval:

21 Dec 2021

Date Issued:

21-Dec-2021

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

29-March-2017

Effective (Date or Lot Number):

21-Dec-2021