

Declaration of Conformity

Certificate Identification: DOC-08P76, 01R60, 08P77, 08P78-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
08P7640	59238	Alinity c-series ICT Reference Solution	Self-declared
01R6070	56676	Alinity c-series Acid Probe Wash	Self-declared
08P7740	56676	Alinity c-series Acid Wash	Self-declared
08P7840	58236	Alinity c-series Alkaline Wash	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, 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:

C. Becker

Full Name:

Claudia Becker

Position:

Director Quality Assurance

Date of Approval:

22 Dec 2021

Signature:

Tiffini Jenkins

Full Name:

Tiffini Jenkins

Position:

Manager Regulatory Affairs

Date of Approval:

21-Dec-21

Date Issued:

22 Dec 2021

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

24-Aug-2018

Effective (Date or Lot Number):

22 Dec 2021