

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