Abbott

Declaration of Conformity

Certificate Identification: DoC-08P32-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
08P3220	60976	Alinity i CA 19-9XR Reagent Kit (2 x 100 Tests)	**Self-declared**
08P3230	60976	Alinity i CA 19-9XR Reagent Kit (2 x 500 Tests)	**Self-declared**
08P3201	38225	Alinity i CA 19-9XR Calibrators	**Self-declared**
08P3210	38224	Alinity i CA 19-9XR 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: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 20 Dec 2021

Signature: Susanne Ulrich
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