Abbott

Declaration of Conformity

Certificate Identification: DoC-04V5121, 04V5131-SD DELK
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
04V5121	53229	Alinity c Total Bilirubin Reagent Kit	**Self-declared**
04V5131	53229	Alinity c Total Bilirubin Reagent Kit	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, 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: **Joerg Amborn**

Position: **Director, Quality Assurance**

Date of Approval: 2020-06-09

Signature: _____

Full Name: **Noah Lermer**

Position: **Director Regulatory Affairs**

Date of Approval: 12-Jun-20

Date Issued: 12-Jun-20

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 27-Feb-2019

Effective (Date or Lot Number): 12-Jun-20