

Declaration of Conformity

Certificate Identification: DoC-06P1401-SD DELK
Legal Manufacturer's Name: Abbott GmbH & Co. KG
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 |
|---------------------------------------|-----------|----------------------------------|----------------|
| 06P1401 | NA | Alinity Reaction Vessels | Self-declared |

| | |
|---|--|
| Authorized European Representative (name and address) | N/A |
| Storage site of technical documentation (name and address) | Abbott Laboratories Diagnostics Division 100 Abbott Park Road, Abbott Park IL USA 60064 |
| 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:

Position:

Date of Approval:

28 Dec 2016

Signature: _____

Full Name:

Position:

Date of Approval:

28 Dec 2016

Date Issued:

28 Dec 2016

Place Issued:

65205 Wiesbaden, Germany

Supersedes:

Not applicable

Effective (Date or Lot Number):

28 Dec 2016