Abbott

Declaration of Conformity

Certificate Identification: DoC-07P47-AII 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
07P4722	52442	Alinity i Toxo IgM Reagent Kit (2 x 100 Tests)	**Annex II List B**
07P4732	52442	Alinity i Toxo IgM Reagent Kit (2 x 500 Tests)	**Annex II List B**
07P4701	42163	Alinity i Toxo IgM Calibrator	**Annex II List B**
07P4710	42164	Alinity i Toxo IgM Controls	**Annex II List B**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom
Notified Body number	**0088**
Approval Certificate No.	**LRQ 0964174**
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, Max-Planck-Ring 2, 65205 Wiesbaden, Germany.
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 IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Manager Quality**
Date of Approval: 06 Mar 2017

Signature: Susanne Ulrich
Full Name: **Susanne Ulrich**
Position: **Senior Manager Regulatory Affairs**
Date of Approval: 03/MAR/2017
Date Issued: 06/Mar/2017
Place Issued: 65205 Wiesbaden, Germany
Supersedes: Not applicable
Effective (Date or Lot Number): 06/ Mar /2017