



Declaration of Conformity

Certificate Identification:
Legal Manufacturer's Name:

02K47 LC
Abbott Laboratories
Diagnostics Division

IRIS V2

Legal Manufacturer's Address:

Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K47-20 2K47-22 2K47-25 2K47-27	58729	ARCHITECT Anti-TPO Reagent Kit	Self-declared
2K47-01	55210	ARCHITECT Anti-TPO Calibrators	Self-declared
2K47-10	55211	ARCHITECT Anti-TPO Controls	Self-declared

Authorized European Representative (Name and Address)	Abbott GmbH & Co. KG Max-Planck-Ring-2 65205 Wiesbaden, Germany
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, Middleton, VA 22645-1905 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:

William H Phillips

Full Name:

William H Phillips

Position: Quality Manager

Date of Approval:

12/09/2014

Date Issued:

12/15/2014

Supersedes:

28 July 2006

Signature:

Mary Owen Musewski

Full Name:

Mary Owen Musewski

Position: Regulatory Affairs Manager

Date of Approval:

12/11/2014

Place Issued:

Abbott Laboratories Diagnostics Div.
Abbott Park, IL 60064 USA

Effective (Date or Lot Number):

12/15/2014