

EU Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

EU Authorized Representative: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name: IMMULITE 2000 Toxoplasma Quantitative IgG

Catalogue Number (REF): L2KTXP2

Siemens Material Number (SMN): 10381323

Classification: ANNEX II, List B

Conformity Assessment Route: ANNEX IV

Notified Body: Lloyd's Register Quality Assurance Ltd.
1 Trinity Park, Bickenhill Lane
Solihull, B37 7ES, UK
Identification No. 0088

Document Identifier: EC DEC_IMM 2000 Toxoplasma Quantitative IgG L2KTXP

Version: 02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Malgorzata Robak
Regulatory Affairs Supervisor
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2019-03-05

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY