

## 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 IgM ( $\mu$ -Capture)

**Catalogue Number (REF):** L2KTZ2

**Siemens Material Number (SMN):** 10381298

**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 IgM ( $\mu$ -Capture) L2KTZ

**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:**

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**Malgorzata Robak**  
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2019-03-01

**Date**  
[YYYY-MM-DD]