

## 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

**Product Name:** IMMULITE 2000 HBsAg

**Catalogue Number (REF):** L2KHB2

**Siemens Material Number (SMN):** 10381306

**Classification:** ANNEX II, List A

**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 HBsAg L2KHB

**Version:** 01

*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:**

Anita Wample  
Head of Quality Management  
Siemens Healthcare Diagnostics Products Ltd.  
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

Date  
[YYYY-MM-DD]