

## 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 HBsAg

**Catalogue Number (REF):** L2KHB2

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

**Classification:** ANNEX II, List A

**Conformity Assessment Route:** ANNEX IV

**Notified Body:** TÜV Rheinland LGA Products GmbH  
Tillystrasse 2  
90431 Nuremberg, Germany  
Identification No. 0197

**Document Identifier:** EC DEC\_IMMULITE® 2000 HBsAg

**Version:** 03

*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:** \_\_\_\_\_ **2019-09-26**

**Malgorzata Robak**  
**Regulatory Affairs Supervisor**  
**Siemens Healthcare Diagnostics Products Ltd.**  
**Llanberis, Gwynedd, LL55 4EL, UK**

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

EU DECLARATION OF CONFORMITY