

## EU Declaration of Conformity



We hereby declare that the products described below conform 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 FSH

**Catalogue Number (REF):** L2KFS2  
L2KFS6

**Siemens Material Number (SMN):** 10381201  
10381180

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 FSH L2KFS

**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:** \_\_\_\_\_ **2019-01-30**

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

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

EU DECLARATION OF CONFORMITY