SIEMENS

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 GI-MA

Catalogue Number (REF): L2KGI2

Siemens Material Number (SMN): 10380988

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 GI-MA L2KGI

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:

2019-01-31

Malgorzata Robak

Regulatory Affairs Supervisor

Siemens Healthcare Diagnostics Products Ltd.

Llanberis, Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD]

