

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 Total IgE

Catalogue Number (REF): L2KIE2
L2KIE6

Siemens Material Number (SMN): 10380873
10380872

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Total IgE L2KIE

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*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: _____ **2019-02-01**
Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd LL55 4EL, UK **Date**
[YYYY-MM-DD]