SIEMENS

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 Free T4

Catalogue Number (REF): L2KFT42

L2KFT46

Siemens Material Number (SMN): 10381678

10381677

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Free T4 L2KFT4

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

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Regulatory Affairs Supervisor

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Date

[YYYY-MM-DD]



