## **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 Calcitonin

Catalogue Number (REF): L2KCL2

Siemens Material Number (SMN): 10381446

Classification: General IVD

Conformity Assessment Route: ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Calcitonin L2KCL

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**: 2019-01-29

Malgorzata Robak Regulatory Affairs Supervisor

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Date [YYYY-MM-DD]