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

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: 01

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:

Kevin Owen

Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.

LLanberis Gwynedd LL55 4EL, UK

2017-06-16

Date [YYYY-MM-DD]