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 Third Generation TSH Control Module

Catalogue Number (REF):

LTGCM

Siemens Material Number (SMN):

10385395

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM Third Generation TSH Control Module LTGCM

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:

Anita Wample

Head of Quality Management

Siemens Healthcare Diagnostics Products Ltd.

LLanberis Gwynedd LL55 4EL, UK

sita Wamde

Date

[YYYY-MM-DD]