

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 Inc.
500 GBC Drive, Maitland, P.O. Box 6101
Newark, DE, 19714, USA

EU Authorized Representative:

Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name:

IMMULITE 2000 Chemiluminescent Substrate Module
L2SUBM

Catalogue Number (REF):

10365232

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Substrate L2SUBM
Version: 07

Signature:

Robak Malgorzata

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.

Digitally signed by Malgorzata Robak
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Date

2019-02-13

[YYYY-MM-DD]

Malgorzata Robak
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EU DECLARATION OF CONFORMITY