

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 Inc.
62 Flanders-Bartley Road
Flinders, NJ, 07636, USA

Place of Manufacture:

CARCO TECHNICAL PLASTICS
Grant Road
Tucson, AZ 85705, USA

Hoover Precision Products
1390 Industrial Park Dr.,
Sault Ste. Marie, MI 49783, USA

EC Authorized Representative:

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

Product Name:

IMMULITE 2000 Systems Reaction Tubes

Catalogue Number (REF):

LRX1

Siemens Material Number (SMN):

10385205

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

Doc IMMULITE 2000 RxnTubes

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Signature:

Ryan Sherrie

Electronically signed by Ryan Sherrie
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This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.

Sherrie Ryan
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Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY