

EU Declaration of Conformity



Siemens Healthcare Diagnostics Inc. hereby declares that the medical device(s) specified on the following page conform(s) to all applicable requirements of REGULATION (EU) 2017/746 for *in vitro* diagnostic medical devices.

Legal Manufacturer

Name and Address	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
Single Registration Number (SRN)	GB-MF-000016339

Place(s) of Manufacture

Name and Address	Siemens Healthcare Diagnostics Inc. 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE, 19714, USA
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Authorized Representative

Name and Address	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Single Registration Number (SRN)	IE-AR-000006763

Common Specifications

Applicable Common Specifications	N/A
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Notified Body

Name and Address	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany
Identification Number	0197
Conformity Assessment Pathway	Annex IX
Certificate(s) Issued	HX 7091840-1

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.

This declaration of conformity supersedes any declaration issued previously for the same product.

On Behalf of Siemens Healthcare Diagnostics Products Ltd:

Signature: 

Electronically signed by: Alan Haley
Reason: I am approving this document
Date: Oct 13, 2022 13:57 EDT

Email: alan.haley@siemens-healthineers.com

Alan Haley
Senior Manager, Regulatory Affairs
Llanberis, Gwynedd, UK

Oct 13, 2022

EU DECLARATION OF CONFORMITY

EU Declaration of Conformity

List of Product(s)

Siemens Material Number (SMN)	Product Name	Catalogue Number (REF)	Legacy Part Number	Configuration / Quantity	Basic UDI-DI	Risk Class
10385232	IMMULITE 2000 Chemiluminescent Substrate Module	L2SUBM	N/A	2 x 205 mL	0405686901421V6	B

Intended Purpose

Siemens Material Number (SMN)	Product Name	Intended Purpose
10385232	IMMULITE 2000 Chemiluminescent Substrate Module	For use in the routine operation of the IMMULITE 2000 Systems, as described in the Operator's Manuals. Chemiluminescent Substrate is a dioxetane-based compound that is intended to be used in all IMMULITE assay reactions to generate light emission for qualitative or quantitative specific-analyte determinations.