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, United Kingdom
Single Registration Number (SRN)	GB-MF-000016339

Place(s) of Manufacture

Name and Address	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, United Kingdom

Authorized Representative

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

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:
Idrissa Sparks-Tillman
Reason: I am approving this document
Date: May 17, 2022 09:47 EDT

Email:

Idrissa Sparks-Tillman
Senior Manager, Regulatory Affairs
Llanberis, Gwynedd, UK

May 17, 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	Basic UDI-DI	Risk Class
10283033	IMMULITE 2000 3g Allergy Specific IgE Sample Diluent	L2UNZ	L2UNZ	0405686900218UY	A

Intended Purpose

Siemens Material Number (SMN)	Product Name	Intended Purpose
10283033	IMMULITE 2000 3g Allergy Specific IgE Sample Diluent	For on-board dilution of samples.