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 Inc. 62 Flanders Bartley Road Flanders, NJ 07836, USA
Single Registration Number (SRN)	US-MF-000016337

Place(s) of Manufacture

Name and Address	Carclo (Latrobe) 600 Depot St, Latrobe, PA 15650, USA

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 Inc..
This declaration of conformity supersedes any declaration issued previously for the same product.
On Behalf of Siemens Healthcare Diagnostics Inc.:

Signature:

Electronically signed by:
Ernest Joseph
Reason: I am approving this document
Date: Mar 18, 2022 17:00 EDT

Email: ernest.joseph@siemens-healthineers.com

Ernest Joseph
Director, Regulatory Affairs
Flanders, New Jersey, USA

Mar 18, 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
10282849	IMMULITE 2000 Allergen Tube Septa	L2ATS2	n/a	0405686900997WR	A

Intended Purpose

Siemens Material Number (SMN)	Product Name	Intended Purpose
10282849	IMMULITE 2000 Allergen Tube Septa	Allergen Tube Septa are used for holding the allergen and loaded into the Allergen wedges for testing purpose, on the IMMULITE 2000 XPi systems.