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 TECHNICAL PLASTICS Grant Road, Tucson AZ 85705, USA
	TN Michigan 1390 Industrial Park Dr., Sault Ste. Marie, MI 49783, 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
10385206	IMMULITE 2000 Systems Reaction Tubes	LRXT	n/a	0405686901003UG	A

Intended Purpose

Siemens Material Number (SMN)	Product Name	Intended Purpose
10385206	IMMULITE 2000 Systems Reaction Tubes	Reaction tubes are used to collect and hold the Bead and they are the entities where the chemi-luminescent reaction takes place as part of the Immuno-Assay testing, on the IMMULITE 2000 XPi systems.