

# 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

<i>Name and Address</i>	Siemens Healthcare Diagnostics Inc. 62 Flanders Bartley Road Flanders, NJ 07836, USA
<i>Single Registration Number (SRN)</i>	US-MF-000016337

## Place(s) of Manufacture

<i>Name and Address</i>	CTP Mitcham 47 Wates Way, Mitcham, Surrey, CR4 4HR, UK
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## Authorized Representative

<i>Name and Address</i>	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
<i>Single Registration Number (SRN)</i>	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.:**

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**EU DECLARATION OF CONFORMITY**

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## List of Product(s)

Siemens Material Number (SMN)	Product Name	Catalogue Number (REF)	Legacy Part Number	Basic UDI-DI	Risk Class
10282837	IMMULITE 2000 Allergen Tube Caps	L2ATC	n/a	0405686900996WP	A

## Intended Purpose

Siemens Material Number (SMN)	Product Name	Intended Purpose
10282837	IMMULITE 2000 Allergen Tube Caps	Allergen tube cap is used to close/seal at the top of an Allergen tube to avoid spillage, on the IMMULITE 2000 XPI systems.