



EU Declaration of Conformity

for IMMULITE 2000/XPi Probe Cleaning Kit

Siemens Healthcare Diagnostics Products GmbH hereby declares conformity to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU for the following In Vitro Diagnostic Device:

Product Name

IMMULITE 2000/XPi Probe Cleaning Kit

Intended Purpose Statement of Device

For use in daily maintenance of the IMMULITE 2000/XPi Systems – to minimize reagent carryover by reducing protein and lipid buildup in the probe.

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
L2KPM	10385229	1 x 100 mL Probe Cleaning Solution 1 x Probe Cleaning Wedge

Basic UDI-DI (Basic Unique Device Identification)

0405686902050UY

Risk classification according to the rules of Annex VIII REGULATION (EU) 2017/746

Class A

Manufacturer and address of registered place of business

Manufacturer	Siemens Healthcare Diagnostics Products GmbH
Single Registration Number	DE-MF-000005039
Address	Emil-von-Behring-Str. 76 35041 Marburg Germany

Notified Body

Name	N/A
Identification Number	N/A
Address	N/A

Conformity Assessment Procedure	Article 48 (10)
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Notified Body Certificate Number

N/A

Common Specifications the product conforms with

Identifier	Title of Document
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N/A	N/A
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This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products GmbH according to REGULATION (EU) 2017/746 for the following In Vitro Diagnostic Device and any other Union legislation as stated in the Conformity with Standards and supersedes any declaration issued previously for the same product.

Signature:

Electronically signed by:
Andreas Wiegand
Reason: I am approving
this document
Date: Mar 8, 2022 13:31
GMT+1

Email: ANDREAS.WIEGAND@SIEMENS-HEALTHINEERS.COM

Andreas Wiegand
Senior Director Regulatory Affairs
Siemens Healthcare Diagnostics Products GmbH
Marburg, Germany

Date Mar 8, 2022