

EU Declaration of Conformity



We hereby declare that the products described below conform to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:

Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture:

Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

EU Authorized Representative:

Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name:

IMMULITE 2000 Thlrd Generation TSH

Catalogue Number (REF):

L2KTS2
L2KTS6

Siemens Material Number (SMN):

10381665
10381667

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Thlrd Generation TSH L2KTS

Version:

02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Robak

Digitally signed by Robak Malgorzata
DN: serialNumber=20030946,
givenName=Malgorzata, sn=Robak, o=Siemens,

Signature:

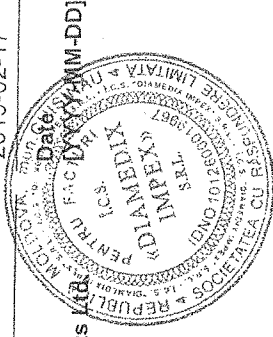
Malgorzata

Cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.17 22:13:33 Z

Malgorzata Robak
Regulatory Affairs Supervisor

Siemens Healthcare Diagnostics Products Ltd
Llanberis, Gwynedd LL55 4EL, UK

2019-02-17



EU Declaration of Conformity



We hereby declare that the products described below conform to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:

Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture:

Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

EU Authorized Representative:

Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name:

IMMULITE 2000 Anti-TPO Ab

Catalogue Number (REF):

L2KTO2

L2KTO6

Siemens

Siemens Material Number (SMN):

10381650

10381649

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Anti-TPO Ab L2KTO

Version:

02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Robak

Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=20020NF,
givenName=Malgorzata, sn=Robak, o=Siemens,
Reason: I am approving this document
Date: 2019.02.04 14:37:08 Z

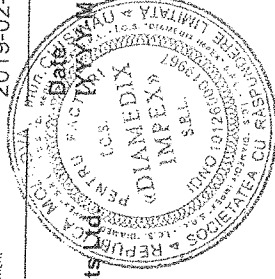
2019-02-04

Malgorzata Robak

Regulatory Affairs Supervisor

Siemens Healthcare Diagnostics Products Ltd.

Llanberis, Gwynedd LL55 4EL, UK



EU Declaration of Conformity



We hereby declare that the products described below conform to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:

Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture:

Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

EU Authorized Representative:

Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name:

IMMULITE 2000 Free T4

Catalogue Number (REF):

L2KFT42
L2KFT46

10

Siemens Material Number (SMN):	10381678
	10381677

Classification:

General IVD

Conformity Assessment Route:

ANEX

Document Identifier:

EC DEC_IMM 2000 Free T4 L2KFT4

Version:

02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product*

Signature:

Robak Małgorzata

Digitally signed by Robak Mulgurizita
DN: serialNumber=2002CNKF,
givenName=Malgurizato, sn=Robak, o=Siemens,
cn=Robak Mulgurizita
Reason: I am approving this document
Date: 2019.01.30 22:40:27 Z

2019-01-30

Małgorzata Robak

Regulatory Affairs Supervisor

Siemens Healthcare Diagnostics P
Llanberis, Gwynedd LL55 4FL, UK



EU Declaration of Conformity



We hereby declare that the products described below conform to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:

Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture:

Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

EU Authorized Representative:

Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name:

IMMULITE® 2000 PSA

Catalogue Number (REF):

L2KPS2, L2KPS6

Siemens Material Number (SMN):

10380986, 10380996

Classification:

ANNEX II, List B

Conformity Assessment Route:

ANNEX IV

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nuremberg, Germany
Identification No. 0197

Document Identifier:

EC DEC_IMMULITE® 2000 PSA

Version:

03

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Robak

Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=200200KPE,
givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
Reason for approving this document
Date: 2019.09.25 09:58:23 +01'00'

2019-09-25

Malgorzata Robak

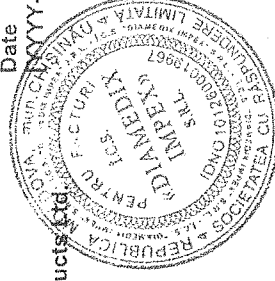
Regulatory Affairs Supervisor

Siemens Healthcare Diagnostics Products Ltd.

Llanberis, Gwynedd, LL55 4EL, UK

Date

2019-09-25



Konformitätserklärung

Declaration of Conformity



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III erfüllt werden.	We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.
---	--

Produktname (deutsch): IMMULITE 2000 / IMMULITE 2500 Waschmodul	Product name (English): IMMULITE 2000 / IMMULITE 2500 Probe Wash Module
--	--

Produkt-Nr. / Product No. (REF):	L2PWSM
----------------------------------	--------

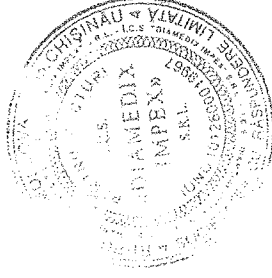
Packungsgröße(n) / Package Size(s) (REF):	L2PWSM
---	--------

IVD-Kategorie / IVD Category: Sonslige	Others
---	--------

Hersteller / Manufacturer:	Siemens Healthcare Diagnostics Products GmbH
----------------------------	--

Adresse (innerhalb Deutschland): Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	Address (international): Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg Germany
---	--

Bestätigung / Authorization:	
Director Quality/Regulatory	
Unterschrift / Signature	
Dr. Jörg Amborn	
Name /Name	
2011-04-14	
Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:	



Konformitätserklärung

Declaration of Conformity



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III erfüllt werden.

We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.

Produktname (deutsch):

IMMULITE 2000 / IMMULITE 2500 Reinigungsmodul

Product name (English):

IMMULITE 2000 / IMMULITE 2500 Probe Cleaning Kit

Produkt-Nr. / Product No. (REF):

L2KPM

Packungsgröße(n) / Package Size(s) (REF):

L2KPM

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

J. A. C.

Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2011-04-05

Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:



SIEMENS

EU Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:

Siemens Healthcare Diagnostics Inc.
62 Flanders-Bartley Road
Flanders, NJ, 07836, USA

Place of Manufacture:

CARCLO TECHNICAL PLASTICS
Grant Road
Tucson, AZ 85705, USA

Hoover Precision Products
1390 Industrial Park Dr.,
Sault Ste. Marie, MI 49783, USA

EC Authorized Representative:

Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name:

IMMULITE 2000 Systems Reaction Tubes

Catalogue Number (REF):

LRXT

Siemens Material Number (SMN):

10385206

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

DoC_IMMULITE 2000_RxnTubes

Version:

4.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Ryan Sherrie

Digitally signed by Ryan Sherrie
DN: serialNumber=200262FR, givenName=Sherrie,
sn=Ryan, o=Siemens, cn=Ryan Sherrie
Date: 2018.05.31 09:12:46 -0400

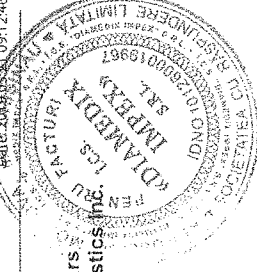
Sherrie Ryan

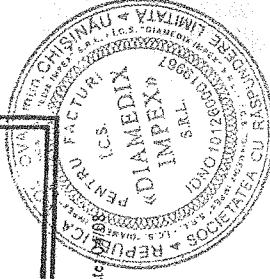
Sr Manager Regulatory Affairs

Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

Date

[YYYY-MM-DD]





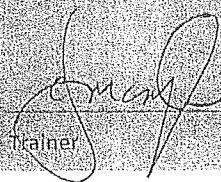
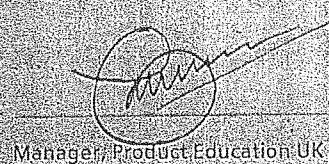
Certificate

Popescu Doru

Has successfully completed the following training:

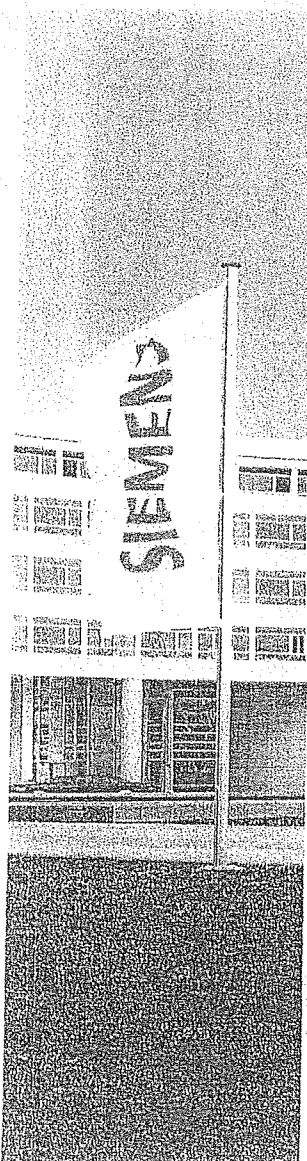
IMMULISTE 2000/2500 Field Service Training (ENEA)

17/01/2011 to 28/01/2011


Trainer
Manager, Product Education UK

www.siemens.com/diagnostics

SIEMENS





Certificate

Nechit Romulus

In recognition of your commitment to continuous
learning and professional development
you have completed:

IMMULITE 2000® Application Training Course

from July 13th to July 15th 2009

Aristeidis Kalpias
Instructor

Answers for life.

SIEMENS