SIEMENS

EU Declaration of Conformity

CE 0197

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 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-HBc
Catalogue Number (REF):	L2KHC2
Siemens Material Number (SMN):	10381311
Classification:	ANNEX II, List A
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 Anti-HBc
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.09.26 22:50:36 +01'00'

2019-09-26

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd, LL55 4EL, UK

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE 0197

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 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-HBs
Catalogue Number (REF):	L2KAH2
Siemens Material Number (SMN):	10381318
Classification:	ANNEX II, List A
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 Anti-HBs
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.08.23 11:49:44 +01'00'

2019-08-23

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd, LL55 4EL, UK

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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 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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.04 14:37:08 Z

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd LL55 4EL, UK

2019-02-04

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

Lyphochek Immunoassay Plus Control

- Offers a vast array of popular routine immunoassay analytes
- Assigned values are available for all major automated analyzers
- Provides a highly efficient solution for laboratories that focus on routine tests
- Human serum based
- 3 year shelf life at 2–8°C
- 7 day reconstituted stability at 2–8°C for most analytes

POCT Methods Listed

Ordering Information

Cat #	Description
370	Trilevel (4 of each level) . . . . . 12 x 5 mL
371	Level 1 . . . . . 12 x 5 mL
372	Level 2 . . . . . 12 x 5 mL
373	Level 3 . . . . . 12 x 5 mL
370X	Trilevel MiniPak (1 of each level) . . . . . 3 x 5 mL

Analytes

25-Hydroxy Vitamin D
11-Deoxycortisol
17-α-Hydroxyprogesterone
Acetaminophen
ACTH
Aldosterone
Alphafetoprotein (AFP)
Amikacin
Amiodarone*
Amitriptyline
Androstenedione
Angiotensin I
Anti-Thyroglobulin (Anti-Tg)*
Anti-Thyroperoxidase (Anti-TPO)*
C-Peptide
Caffeine
Calcitonin
Carbamazepine
Carbamazepine (Free)**
CEA
Chloramphenicol
Cortisol
Cyclosporine*
Desipramine**
DHEA
DHEA Sulfate
Digoxin
Disopyramide
Estradiol
Estriol (Free)
Estriol (Total)*
Estrogen (Total)
Ethosuximide
Ferritin
Flecainide**
Folate
Fructosamine**
FSH
Gastrin
Gentamicin**
Glucagon*
hCG
hCG-β Subunit
hGH
Imipramine
Immunoglobulin A (IgA)
Immunoglobulin E (IgE)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Immunoreactive Trypsinogen (IRT)*
Insulin
Iron
Iron (TIBC)
LH
Lidocaine
Lithium
N-Acetylprocainamide (NAPA)
Netilmicin*
Nortriptyline
P/P
Phenobarbital
Phenytoin
Phenytoin (Free)**
Primidone
Procainamide
Progesterone
Prolactin
Propranolol**
PSA
PSA (Free)
PTH (Intact)*
Quinidine**
Salicylate
SHBG (Sex Hormone Binding Globulin)*
Somatomedin-C
T3 (Free)
T3 (Total)
T3 Uptake/T-Uptake
T4 (Free)
T4 (Total)
TBG
Testosterone
Testosterone (Free)
Theophylline
Thyroglobulin (Tg)
Tobramycin
Tricyclic Antidepressants (TCA) Screen**
TSH
Valproic Acid
Valproic Acid (Free)**
Vancomycin
Vitamin B_{12}

*No claims are made regarding performance or stability.
**Values are not provided.

Did you know...
The Lyophilized form of this control provides convenience in transportation and a longer shelf life.

Refer to myqcevents.com or the package insert of currently available lots for specific analyte and stability claims.

Lyphochek Immunoassay Plus Control

- Offers a vast array of popular routine immunoassay analytes
- Assigned values are available for all major automated analyzers
- Provides a highly efficient solution for laboratories that focus on routine tests
- Human serum based
- 3-year shelf life at 2–8°C
- 7 day reconstituted stability at 2–8°C for most analytes

POCT Methods Listed

Ordering Information

Cat #	Description
370	Trilevel (4 of each level) . . . . . 12 x 5 mL
371	Level 1 . . . . . 12 x 5 mL
372	Level 2 . . . . . 12 x 5 mL
373	Level 3 . . . . . 12 x 5 mL
370X	Trilevel MiniPak (1 of each level) . . . . . 3 x 5 mL

Analytes

25-Hydroxy Vitamin D
11-Deoxycortisol
17-α-Hydroxyprogesterone
Acetaminophen
ACTH
Aldosterone
Alphafetoprotein (AFP)
Amikacin
Amiodarone*
Amitriptyline
Androstenedione
Angiotensin I
Anti-Thyroglobulin (Anti-Tg)*
Anti-Thyroperoxidase (Anti-TPO)*
C-Peptide
Caffeine
Calcitonin
Carbamazepine
Carbamazepine (Free)**
CEA
Chloramphenicol
Cortisol
Cyclosporine*
Desipramine**
DHEA
DHEA Sulfate
Digoxin
Disopyramide
Estradiol
Estriol (Free)
Estriol (Total)*
Estrogen (Total)
Ethosuximide
Ferritin
Flecainide**
Folate
Fructosamine**
FSH
Gastrin
Gentamicin**
Glucagon*
hCG
hCG-β Subunit
hGH
Imipramine
Immunoglobulin A (IgA)
Immunoglobulin E (IgE)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Immunoreactive Trypsinogen (IRT)*
Insulin
Iron
Iron (TIBC)
LH
Lidocaine
Lithium
N-Acetylprocainamide (NAPA)
Netilmicin*
Nortriptyline
PAP
Phenobarbital
Phenytoin
Phenytoin (Free)**
Primidone
Procainamide
Progesterone
Prolactin
Propranolol**
PSA
PSA (Free)
PTH (Intact)*
Quinidine**
Salicylate
SHBG (Sex Hormone Binding Globulin)*
Somatomedin-C
T3 (Free)
T3 (Total)
T3 Uptake/T-Uptake
T4 (Free)
T4 (Total)
TBG
Testosterone
Testosterone (Free)
Theophylline
Thyroglobulin (Tg)
Tobramycin
Tricyclic Antidepressants (TCA) Screen**
TSH
Valproic Acid
Valproic Acid (Free)**
Vancomycin
Vitamin B_{12}

*No claims are made regarding performance or stability.
**Values are not provided.

Did you know...
The Lyophilized form of this control provides convenience in transportation and a longer shelf life.

Refer to mybiosource.com or the package insert of currently available lots for specific analyte and stability claims.

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of:

Bio-Rad Laboratories

2000 Alfred Nobel Drive
Hercules CA 94547
United States of America

Central function listed above. See appendix for additional locations

applicable to:

The design, development, manufacture, and distribution of reagents and analytical instruments. The installation and servicing of analytical instruments

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 13485:2016

Certificate Number:	17622
EAC Code:	12, 19
Certified Since:	July 9, 2018
Valid Until:	July 8, 2021
Reissued:	August 2, 2018
Cycle Issued:	July 9, 2018

For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

Certificate of Registration

nqa global assurance

Appendix to Certificate Number: 17622

Includes Facilities Located at:

Bio-Rad Laboratories Certificate Number 17622 2000 Alfred Nobel Drive Hercules CA 94547 United States of America	Design and development of reagents, plastic consumables and analytical instruments, LSG Executive management
Bio-Rad Laboratories (Singapore) Pte. Ltd. Certificate Number 17622 1 Kaki Bukit View #03-01 Techview 415941 Republic of Singapore	Manufacture of analytical instruments and chemicals
Bio-Rad Laboratories Certificate Number 17622 255/265 Linus Pauling Drive Hercules CA 94547 United States of America	Installation, service and repair of analytical instruments, Technical Support, Complaint Handling
Bio-Rad Laboratories Certificate Number 17622 925 Alfred Nobel Drive Hercules CA 94547 United States of America	Manufacture of reagents

Certified Since: July 9, 2018
Valid Until: July 8, 2021
Reissued: August 2, 2018
Cycle Issued: July 9, 2018

Certificate of Registration

nqa global assurance

Appendix to Certificate Number: 17622

Includes Facilities Located at:

Bio-Rad Laboratories
Certificate Number 17622
2500 Atlas Road
Richmond CA 94806
United States of America

Distribution of reagents, plastic consumables and analytical instruments

Bio-Rad Laboratories
Certificate Number 17622
487 Aviation Blvd., #100
Santa Rosa CA 95403
United States of America

Manufacture of injection molded plastic consumables

Bio-Rad Laboratories
Certificate Number 17622
3110 Regatta Boulevard
Richmond CA 94804
United States of America

Manufacture of reagents

Bio-Rad Laboratories
Certificate Number 17622
6000 James Watson Drive
Hercules CA 94547
United States of America

Manufacture of analytical instruments

Certified Since: July 9, 2018
Valid Until: July 8, 2021
Reissued: August 2, 2018
Cycle Issued: July 9, 2018

SIEMENS

EU Declaration of Conformity

CE

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 Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE, 19714, USA
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE 2000 Chemiluminescent Substrate Module
Catalogue Number (REF):	L2SUBM
Siemens Material Number (SMN):	10385232
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Substrate L2SUBM
Version:	07

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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.13 23:32:19 Z

2019-02-13

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE 0197

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 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:	IIMMULITE® 2000 Free PSA
Catalogue Number (REF):	L2KPF2
Siemens Material Number (SMN):	10380984
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 Free 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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.09.23 08:50:48 +01'00'

2019-09-23

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd, LL55 4EL, UK

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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 T3
Catalogue Number (REF):	L2KF32 L2KF36
Siemens Material Number (SMN):	10381675 10381682
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Free T3 L2KF3
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.01.30 22:50:39 Z

2019-01-30

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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
Siemens Material Number (SMN):	10381678 10381677
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
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 Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.01.30 22:40:27 Z

2019-01-30

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE 0197

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 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 HBsAg
Catalogue Number (REF):	L2KHB2
Siemens Material Number (SMN):	10381306
Classification:	ANNEX II, List A
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 HBsAg
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.09.26 22:54:24 +01'00'

2019-09-26

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd, LL55 4EL, UK

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

Siemens Healthcare Diagnostics Products GmbH

Konformitätserklärung — *Declaration of Conformity*

CE

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):	***Product name (English):***
IMMULITE 2000 / IMMULITE 2500 Reinigungsmodul	*IMMULITE 2000 / IMMULITE 2500 Probe Cleaning Kit*

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

L2KPM

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

L2KPM

IVD-Kategorie / *IVD Category*:

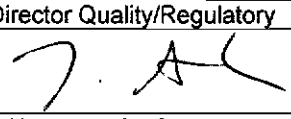
Sonstige	*Others*

Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	***Address** (international):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*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*
2011-04-05
Datum [JJJJ-MM-TT] / *Date [YYYY-MM-DD]:*

SIEMENS

Siemens Healthcare Diagnostics
Products GmbH

Konformitätserklärung

Declaration of Conformity

CE

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):	***Product name (English):***
IMMULITE 2000 / IMMULITE 2500 Waschmodul	*IMMULITE 2000 / IMMULITE 2500 Probe Wash Module*

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

L2PWSM

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

L2PWSM

IVD-Kategorie / *IVD Category*:

Sonstige	*Others*

Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

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

SIEMENS

EU Declaration of Conformity

CE 0197

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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am 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 [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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 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 Third Generation TSH Sample Diluent
Catalogue Number (REF):	L2TSZ
Siemens Material Number (SMN):	10387061
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Third Generation TSH Sample Diluent L2TSZ
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.10 22:56:10 Z

2019-02-10

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd, LL55 4EL, UK

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY