

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 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: _____ **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



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.

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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

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This declaration supersedes any declaration issued previously for the same product.*

Signature:

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

2019-08-23

Date
[YYYY-MM-DD]

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 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:	2019-02-04
Malgorzata Robak Regulatory Affairs Supervisor Siemens Healthcare Diagnostics Products Ltd. Llanberis, Gwynedd LL55 4EL, UK	Date [YYYY-MM-DD]

Lyphocheck 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

POC 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	DHEA	Immunoglobulin M (IgM)	Salicylate
11-Deoxycortisol	DHEA Sulfate	Immunoreactive Trypsinogen (IRT)*	SHBG (Sex Hormone Binding Globulin)*
17- α -Hydroxyprogesterone	Digoxin	Insulin	Somatostatin-C
Acetaminophen	Disopyramide	Iron	T3 (Free)
ACTH	Estradiol	Iron (TIBC)	T3 (Total)
Aldosterone	Estradiol (Free)	U4	T3 Uptake/T ₄ -Uptake
Alpha-fetoprotein (AFP)	Estradiol (Total)*	Lidocaine	T4 (Free)
Amikacin	Estrone (Total)	Lithium	T4 (Total)
Amlodipine*	Ethoxizolam	N-Acetylprocainamide (NAPA)	TBG
Amitriptyline	Feritin	Netilmicin*	Testosterone
Androstenedione	Fentanyl	Nortriptyline	Testosterone (Free)
Angiotensin I	Foliate	PAP	Theophylline
Anti-Thyroglobulin (Anti-Tg)*	Fructosamine**	Phenobarbital	Thyroglobulin (Tg)
Anti-Thyroxine (Anti-TPO)*	FSH	Phenylephrine	Tobramycin
C-Peptide	Gastrin	Phenylephrine (Free)**	Tricyclic Antidepressants (TCA) Screen**
Caffeine	Gentamicin**	Primidone	TSH
Calcitonin	Glucagon*	Procainamide	Valproic Acid
Carbamazepine	HCG	Progesterone	Valproic Acid (Free)**
Carbamazepine (Free)**	HCG- β Subunit	Prolactin	Vancomycin
CEA	hGH	Propranolol**	Vitamin B ₁₂
Chloramphenicol	Imipramine	PSA	
Cortisol	Immunoglobulin A (IgA)	PSA (Free)	
Cyclosporine*	Immunoglobulin E (IgE)	PTH (Intact)*	
Diazepam**	Immunoglobulin G (IgG)	Quinidine**	

*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.

Lyphocheck 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

POOT 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-Thyroxine (Anti-TPO)*
C-Peptide
Caffeine
Calcitonin
Carbamazepine
Carbamazepine (Free)**
CEA
Chloramphenicol
Cortisol
Cyclosporine*
Desipramine**

OHEA
OHEA Sulfate
Digoxin
Disopyramide
Estradiol
Estradiol (Free)
Estradiol (Total)*
Estrogen (Total)
Ethosuximide
Fentanyl
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 B₁₂

*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.



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

A handwritten signature in black ink, likely belonging to a representative of NQA, USA.

For and on behalf of NQA, USA



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

Certificate of Registration



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



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

EU Declaration of Conformity



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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:

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

2019-02-13

Date
[YYYY-MM-DD]

EU Declaration of Conformity



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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

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Signature: _____ **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



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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

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Signature:

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

2019-01-30

Date
[YYYY-MM-DD]

EU Declaration of Conformity



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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:	Malgorzata Robak Regulatory Affairs Supervisor Siemens Healthcare Diagnostics Products Ltd. Llanberis, Gwynedd LL55 4EL, UK	2019-01-30 Date [YYYY-MM-DD]
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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 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

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Signature: _____ **2019-09-26**

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

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.
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Produktname (deutsch): IMMULITE 2000 / IMMULITE 2500 Reinigungsmodul	Product name (English): IMMULITE 2000 / IMMULITE 2500 Probe Cleaning Kit
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Produkt-Nr. / Product No. (REF): L2KPM
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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
Unterschrift / Signature
Dr. Jörg Amborn
Name /Name
2011-04-05
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 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:

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

Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2011-04-14

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

EU Declaration of Conformity



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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

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Signature:

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



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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:		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