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
Product Name:	IMMULITE 2000 C-Peptide
Catalogue Number (REF):	L2KPEP2
Siemens Material Number (SMN):	10381450
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 C-Peptide L2KPEP
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date
[YYYY-MM-DD] 2018-08-24

REPUBLICA MOLDOVA, mun. CHIŞINĂU I.C.S. PENTRU FACTURI «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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
Product Name:	IMMULITE 2000 Thyroglobulin
Catalogue Number (REF):	L2KTY2
Siemens Material Number (SMN):	10381648
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Thyroglobulin L2KTY
Version:	01

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: Anita Wample 2016-08-26

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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
Product Name:	IMMULITE 2000 Insulin
Catalogue Number (REF):	L2KIN2 L2KIN6
Siemens Material Number (SMN):	10381455 10381456
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Insulin L2KIN
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
Llanberis Gwynedd, LL55 4EL, UK

Date [YYYY-MM-DD] 2016-11-18

REPUBLICA MOLDOVA mun. CHISINAU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019961 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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 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]:*

REPUBLICA MOLDOVA, mun. CHIȘINĂU
PENTRU FACTURĂ
I.C.S. «DIAMEDIA IMPEX» S.R.L.
IDNO 1012600018967
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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*:

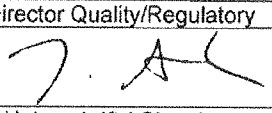
Sonstige	*Others*

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]:*

EC Declaration of Conformity
according to directive 98/79/EC, Annex III

Manufacturer:

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900
U.S.A.

We declare under sole responsibility that the following device to which this declaration relates, meets the essential health and safety requirements and is in conformity with the relevant sections of applicable EC standards and other normative documents. If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.

Device type:	**In Vitro Diagnostic Medical Device**
Device name:	**IMMULITE® 2000 Chemiluminescent Substrate**
Catalog number:	**L2SUBM**
National and other standards and technical specifications:	**EN 375, EN 980, ISO 13485, EN 13612, EN 13640, EN 13641, ISO 14971, ISO/IEC 17050-1, 2, EN 17511, 21 CFR 820**
EU Representative:	**Siemens Healthcare Diagnostics Limited** **Faraday House** **Sir William Siemens Square, Frimley** **Camberley, GU16 8QD** **United Kingdom**

Signature/Date of Manufacturer or Responsible Party: _____ (Signature) 08/17/09 (Date)

Name/Title of Signatory: Kambiz Drake (Print Name) Dir. of QA-Los Angeles (Title)

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 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

REPUBLICA MOLDOVA mun. CHIŞINĂU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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=Z0026ZFR, givenName=Sherrie, sn=Ryan, o=Siemens, cn=Ryan Sherrie
Date: 2019.05.21 09:12:46 -04'00'

Sherrie Ryan
Sr Manager Regulatory Affiars
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

Date
[YYYY-MM-DD]

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'

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

Date [YYYY-MM-DD] 2019-09-26

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
Product Name:	IMMULITE 2000 AlaTOP
Catalogue Number (REF):	L2KAT2
Siemens Material Number (SMN):	10380878
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 AlaTOP L2KAT
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 PENTRU FACTURI

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
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:	01

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: Anita Wample 2016-08-24

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD]

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
Product Name:	IMMULITE 2000 Anti-TG Ab
Catalogue Number (REF):	L2KTG2 L2KTG6
Siemens Material Number (SMN):	10381659 10381655
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Anti-TG Ab L2KTG
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date 2016-08-22
[YYYY-MM-DD]

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
Product Name:	IMMMULITE 2000 FSH
Catalogue Number (REF):	L2KFS2 L2KFS6
Siemens Material Number (SMN):	10381201 10381180
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 FSH L2KFS
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date
[YYYY-MM-DD] 2010-08-24

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
Product Name:	IMMULITE 2000 Estradiol
Catalogue Number (REF):	L2KE22 L2KE26
Siemens Material Number (SMN):	10381178 10381177
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Estradiol L2KE2
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date
[YYYY-MM-DD] 2016-08-22

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
Product Name:	IMMULITE 2000 CEA
Catalogue Number (REF):	L2KCE2 L2KCE6
Siemens Material Number (SMN):	10380994 10380995
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 CEA L2KCE
Version:	01

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: Anita Wimple for Kevin Owen

Date [YYYY-MM-DD] 2017-03-29

Kevin Owen
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

MOLDOVA, REPUBLICA ... I.C.S. IMPEX» S.R.L. IDNO 1012600019967 SOCIETATE CU RASPUNDERE LIMITATA

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 Herpes I & II IgG
Catalogue Number (REF):	L2KHVG6
Siemens Material Number (SMN):	10381333
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Herpes I & II IgG L2KHVG
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: 2019.02.01 10:21:10 Z

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

2019-02-01

Date
[YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE
0088

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:	Lloyd's Register Quality Assurance Ltd. 1 Trinity Park, Bickenhill Lane Solihull, B37 7ES, UK Identification No. 0088
Document Identifier:	EC DEC_IMM 2000 HBsAg L2KHB
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: 2019.03.04 10:09:38 Z

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

2019-03-04
Date [YYYY-MM-DD]

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
Product Name:	IMMULITE 2000 GI-MA
Catalogue Number (REF):	L2KGI2
Siemens Material Number (SMN):	10380988
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 GI-MA L2KGI
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-24

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967

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
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:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-24

Date
[YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE 0088

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
Product Name:	IMMULITE 2000 Toxoplasma IgM (µ-Capture)
Catalogue Number (REF):	L2KTZ2
Siemens Material Number (SMN):	10381298
Classification:	ANNEX II, List B
Conformity Assessment Route:	ANNEX IV
Notified Body:	Lloyd's Register Quality Assurance Ltd. 1 Trinity Park, Bickenhill Lane Solihull, B37 7ES, UK Identification No. 0088
Document Identifier:	EC DEC_IMM 2000 Toxoplasma IgM (µ-Capture) L2KTZ
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2016-08-22

SIEMENS

EU Declaration of Conformity

CE 0088

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
Product Name:	IMMULITE 2000 Toxoplasma Quantitative IgG
Catalogue Number (REF):	L2KTXP2
Siemens Material Number (SMN):	10381323
Classification:	ANNEX II, List B
Conformity Assessment Route:	ANNEX IV
Notified Body:	Lloyd's Register Quality Assurance Ltd. 1 Trinity Park, Bickenhill Lane Solihull, B37 7ES, UK Identification No. 0088
Document Identifier:	EC DEC_IMM 2000 Toxoplasma Quantitative IgG L2KTXP
Version:	01

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:

Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

Date
[YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE 0088

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
Product Name:	IMMULITE/IMMULITE 2000 Free PSA
Catalogue Number (REF):	L2KPF2
Siemens Material Number (SMN):	10380984
Classification:	ANNEX II, List B
Conformity Assessment Route:	ANNEX IV
Notified Body:	Lloyd's Register Quality Assurance Ltd. 1 Trinity Park, Bickenhill Lane Solihull, B37 7ES, UK Identification No. 0088
Document Identifier:	EC DEC_IMM 2000 Free PSA L2KPF
Version:	01

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:

Anita Wample

2016-08-22

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE 0088

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
Product Name:	IMMULITE 2000 CMV IgM
Catalogue Number (REF):	L2KCM2
Siemens Material Number (SMN):	10381320
Classification:	ANNEX II, List B
Conformity Assessment Route:	ANNEX IV
Notified Body:	Lloyd's Register Quality Assurance Ltd. 1 Trinity Park, Bickenhill Lane Solihull, B37 7ES, UK Identification No. 0088
Document Identifier:	EC DEC_IMM 2000 CMV IgM L2KCM
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-19

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA mun. CHIŞINĂU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1011600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

EU Declaration of Conformity

CE 0088

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
Product Name:	IMMULITE 2000 CMV IgG
Catalogue Number (REF):	L2KCVG2
Siemens Material Number (SMN):	10381309
Classification:	ANNEX II, List B
Conformity Assessment Route:	ANNEX IV
Notified Body:	Lloyd's Register Quality Assurance Ltd. 1 Trinity Park, Bickenhill Lane Solihull, B37 7ES, UK Identification No. 0088
Document Identifier:	EC DEC_IMM 2000 CMV IgG L2KCVG
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2016-08-22

REPUBLICA MOLDOVA I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019867 SOCIETATEA CU RĂSPUNDERE LIMITATĂ PENTRU FACTURI

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
Product Name:	IMMULITE 2000 Total IgE
Catalogue Number (REF):	L2KIE2 L2KIE6
Siemens Material Number (SMN):	10380873 10380872
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Total IgE L2KIE
Version:	01

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:

Kevin Owen
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2017-02-16
Date
[YYYY-MM-DD]

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
Product Name:	IMMULITE 2000 H. pylori IgG
Catalogue Number (REF):	L2KHPG2 L2KHPG6
Siemens Material Number (SMN):	10381336 10381335
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 H. pylori IgG L2KHPG
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2016-08-22

I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967

SIEMENS

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
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:	Lloyd's Register Quality Assurance Ltd. 1 Trinity Park, Bickenhill Lane Solihull, B37 7ES, UK Identification No. 0088
Document Identifier:	EC DEC_IMM 2000 Anti-HBs L2KAH
Version:	01

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:

Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

Date
[YYYY-MM-DD]

SIEMENS

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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
Product Name:	IMMULITE 2000 3g Allergy Specific IgE Universal Kit
Catalogue Number (REF):	L2KUN6
Siemens Material Number (SMN):	10380875
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 3g Allergy Specific IgE Universal Kit L2KUN
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2016-08-24

SIEMENS

EU Declaration of Conformity

CE

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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
Product Name:	IMMULITE 2000 Unconjugated Estriol (UE3)
Catalogue Number (REF):	L2KUE32 L2KUE36
Siemens Material Number (SMN):	10381192 10381171
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Unconjugated Estriol L2KUE3
Version:	01

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:

Kevin Owen
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2017-06-16

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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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
Product Name:	IMMULITE 2000 Total Testosterone
Catalogue Number (REF):	L2KTW2 L2KTW6
Siemens Material Number (SMN):	10381190 10381191
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Total Testosterone L2KTW
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-24
Date
[YYYY-MM-DD]

SIEMENS

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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
Product Name:	IMMULITE 2000 PAPP-A
Catalogue Number (REF):	L2KPC2
Siemens Material Number (SMN):	10381213
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 PAPP-A L2KPC
Version:	01

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: Anita Wample 2016-08-24

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date
[YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

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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
Product Name:	IMMULITE 2000 Progesterone
Catalogue Number (REF):	L2KPW2 L2KPW6
Siemens Material Number (SMN):	10381181 10381170
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Progesterone L2KPW
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2008-04-24

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
Product Name:	IMMULITE 2000 HCG
Catalogue Number (REF):	L2KCG2 L2KCG6
Siemens Material Number (SMN):	10381206 10381194
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 HCG L2KCG
Version:	01

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: Anita Wample for Kevin Owen 2017-03-29

Kevin Owen
Head of Quality Management
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
Product Name:	IMMULITE 2000 Intact PTH
Catalogue Number (REF):	L2KPP2 L2KPP6
Siemens Material Number (SMN):	10381441 10381442
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Intact PTH L2KPP
Version:	01

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:

Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-06-24

Date
[YYYY-MM-DD]

SIEMENS

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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
Product Name:	IMMULITE 2000 LH
Catalogue Number (REF):	L2KLH2 L2KLH6
Siemens Material Number (SMN):	10381211 10381212
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 LH L2KLH
Version:	01

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:

Anita Wample

2016-08-24

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date
[YYYY-MM-DD]

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 Prolactin
Catalogue Number (REF):	L2KPR2 L2KPR6
Siemens Material Number (SMN):	10381200 10381199
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Prolactin L2KPR
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: 2019.02.17 23:41:42 Z

2019-02-17

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

Date [YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE

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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
Product Name:	IMMULITE 2000 ACTH
Catalogue Number (REF):	L2KAC2
Siemens Material Number (SMN):	10381468
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 ACTH L2KAC
Version:	01

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:

Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

Date [YYYY-MM-DD]

I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019987

DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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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
Product Name:	IMMULITE 2000 Free Beta HCG
Catalogue Number (REF):	L2KFB2
Siemens Material Number (SMN):	10381175
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Free Beta HCG L2KFB
Version:	01

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:

Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

Date
[YYYY-MM-DD]

SIEMENS

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
Product Name:	IMMULITE 2000 Folic Acid
Catalogue Number (REF):	L2KFO2 L2KFO6
Siemens Material Number (SMN):	10380911 10380912
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Folic Acid L2KFO
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2016-08-22

SIEMENS

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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
Product Name:	IMMULITE 2000 Vitamin B12
Catalogue Number (REF):	L2KVB2 L2KVB6
Siemens Material Number (SMN):	10380914 10380913
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Vitamin B12 L2KVB
Version:	01

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:

Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-24

Date
[YYYY-MM-DD]

SIEMENS

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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
Product Name:	IMMULITE 2000 Pyrilinks-D
Catalogue Number (REF):	L2KPD2
Siemens Material Number (SMN):	10381461
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Pyrilinks-D L2KPD
Version:	01

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: Anita Wample — 2016-08-24

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date
[YYYY-MM-DD]

SIEMENS

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
Product Name:	IMMULITE 2000 Osteocalcin
Catalogue Number (REF):	L2KON2
Siemens Material Number (SMN):	10381477
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Osteocalcin L2KON
Version:	01

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:

2017-07-05

Kevin Owen
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
Llanberis Gwynedd, LL55 4EL, UK

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

SIEMENS

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
Product Name:	IMMULITE 2000 Homocysteine
Catalogue Number (REF):	L2KHO2
Siemens Material Number (SMN):	10381040
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Homocysteine L2KHO
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2016-08-24

SIEMENS

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
Product Name:	IMMULITE 2000 Growth Hormone (hGH)
Catalogue Number (REF):	L2KGRH2
Siemens Material Number (SMN):	10381451
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Growth Hormone (hGH) L2KGRH
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-24

Date
[YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

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Place of Manufacture:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
Product Name:	IMMULITE 2000 Cortisol
Catalogue Number (REF):	L2KCO2 L2KCO6
Siemens Material Number (SMN):	10381476 10381480
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Cortisol L2KCO
Version:	01

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: Anita Wamde for Kevin Owen

Kevin Owen
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2012-03-29
Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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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
Product Name:	IMMULITE 2000 Calcitonin
Catalogue Number (REF):	L2KCL2
Siemens Material Number (SMN):	10381446
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Calcitonin L2KCL
Version:	01

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:

2017-06-16

Kevin Owen
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIȘINĂU, PENTRU FACTURI, I.C.S. „DIAMEDIX IMPEX" S.R.L., IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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
Product Name:	IMMULITE 2000 BR-MA
Catalogue Number (REF):	L2KBR2
Siemens Material Number (SMN):	10380983
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 BR-MA L2KBR
Version:	01

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:

Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU FACTURI
I.C.S.
«DIAMEDIX IMPEX»
S.R.L.
IDNO 1012600019967
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

EC 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
Product Name:	IMMULITE 2000 EBV-VCA IgM
Catalogue Number (REF):	L2KEM2
Siemens Material Number (SMN):	10488005
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	EC DEC_IMM2000 EBV-VCA IgM L2KEM
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
Llanberis Gwynedd, LL55 4EL, UK

2015-03-03
Date
[YYYY-MM-DD]

EC 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
Product Name:	IMMULITE 2000 D-Dimer
Catalogue Number (REF):	L2KDD2
Siemens Material Number (SMN):	10381041
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 D-Dimer L2KDD
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-24

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019957

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
Product Name:	IMMULITE 2000 DHEA-SO4
Catalogue Number (REF):	L2KDS2
Siemens Material Number (SMN):	10381193
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 DHEA-SO4 L2KDS
Version:	01

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:

Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

Date
[YYYY-MM-DD]

SIEMENS

EC 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
Product Name:	IMMULITE 2000 EBV-EBNA IgG
Catalogue Number (REF):	L2KEB2
Siemens Material Number (SMN):	10381307
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	EC DOC_IMM2000 EBV-EBNA IgG L2KEB
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
Llanberis Gwynedd, LL55 4EL, UK

Date [YYYY-MM-DD] 2017-03-

EC DECLARATION OF CONFORMITY

SIEMENS

EC 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
Product Name:	IMMULITE 2000 EBV-VCA IgG
Catalogue Number (REF):	L2KVG2
Siemens Material Number (SMN):	10381330
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	EC DEC_IMM2000 EBV-VCA IgG L2KVG
Version:	01

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: Anita Wample 2015-03-03

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
Llanberis Gwynedd, LL55 4EL, UK

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

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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
Product Name:	IMMULITE 2000 OM-MA
Catalogue Number (REF):	L2KOP2
Siemens Material Number (SMN):	10380972
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 OM-MA L2KOP
Version:	01

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: Anita Wample — 2016-08-24

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD]

SIEMENS

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
Product Name:	IMMULITE 2000 AFP
Catalogue Number (REF):	L2KAP2 L2KAP6
Siemens Material Number (SMN):	10381187 10381184
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 AFP L2KAP
Version:	01

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: Anita Wample 2016-08-22

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD]

SIEMENS

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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
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:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2016-08-23

MOLDOVA I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967

SIEMENS

EU Declaration of Conformity

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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
Product Name:	IMMULITE 2000 Third 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 Third Generation TSH L2KTS
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2018-08-24

SIEMENS

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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
Product Name:	IMMULITE 2000 Total T3
Catalogue Number (REF):	L2KT32 L2KT36
Siemens Material Number (SMN):	10381654 10381657
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Total T3 L2KT3
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2016-08-24

SIEMENS

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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
Product Name:	IMMULITE 2000 Total T4
Catalogue Number (REF):	L2KT42 L2KT46
Siemens Material Number (SMN):	10381685 10381664
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Total T4 L2KT4
Version:	01

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: Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

Date [YYYY-MM-DD] 2018-08-21

SIEMENS

EU Declaration of Conformity

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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 D-Dimer Control Module
Catalogue Number (REF):	LDDCM
Siemens Material Number (SMN):	10385330
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM D-Dimer Control Module LDDCM
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: 2019.02.27 22:22:53 Z

2019-02-27

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

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU, I.C.S. «DIAMEDIX IMPEX» S.R.L., PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

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
Product Name:	IMMULITE 2000 Ferritin
Catalogue Number (REF):	L2KFE2 L2KFE6
Siemens Material Number (SMN):	10380908 10380906
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Ferritin L2KFE
Version:	01

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:

Anita Wample

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU FACTURI
I.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600019967
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

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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 Names:	See *List of Products*
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DOC_Mold Allergens
Version:	3.0

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: 2019.02.28 16:33:21 Z

2019-02-28

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

Date [YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulite 2000 Aspergillus oryzae Specific Allergen	M304L2	10386029
Immulite 2000 Phoma betae Specific Allergen	M13L2	10386014
Immulite 2000 Mold Panel 1 Specific Allergen	MP1L4	10386048
Immulite 2000 Botrytis Cinerea Specific Allergen	M7L2	10386044
Immulite 2000 Aspergillus clavatus Specific Allergen	M312L2	10386034
Immulite 2000 Aspergillus flavus Specific Allergen	M311L2	10386033
Immulite 2000 Trichoderma Viride Specific Allergen	M15L2	10386016
Immulite 2000 Epicoccum purpurascens Specific Allergen	M14L2	10386015
Immulite 2000 Pityrosporum orbiculare Specific Allergen	M70L2	10386043
Immulite 2000 Aspergillus nidulans Specific Allergen	M310L2	10386032
Immulite 2000 Stemphylium Solani Specific Allergen	M88L2	10360577
Immulite 2000 Cladosporium herbarum Specific Allergen	M2L4	10386027
Immulite 2000 fusariusm Monilliforme Specific Allergen	M9L2	10386046
Immulite 2000 Rhizopus nigricans Specific Allergen	M11L2	10386012
Immulite 2000 Curvularia lunata Specific Allergen	M16L2	10386017
Immulite 2000 Penicillium notatum Specific Allergen	M1L4	10386019
Immulite 2000 Aspergillus niger Specific Allergen	M207L2	10386023
Immulite 2000 Helminthosporium halodes Specific Allergen	M8L2	10386045
Immulite 2000 Alternaria tenuis Specific Allergen	M6L4	10386042
Immulite 2000 Mucor racemosus Specific Allergen	M4L2	10386038
Immulite 2000 Stemphylium botryosum Specific Allergen	M10L2	10386011
Immulite 2000 Aureobasidium pullulans Specific Allergen	M12L2	10386013
Immulite 2000 Candida albicans Specific Allergen	M5L4	10386040
Immulite 2000 Hormodendrum hordei Specific Allergen	M45L2	10386037
Immulite 2000 Chaetomium globosum Specific Allergen	M208L2	10386024
Immulite 2000 Cephalosporium acremonium Specific Allergen	M202L2	10386020
Immulite 2000 Aspergillus terres Specific Allergen	M309L2	10386031
Immulite 2000 Eurotium Specific Allergen	M300L2	10386028
Immulite 2000 Micropolyspora faeni Specific Allergen	M212L2	10386025
Immulite 2000 Trichosporon pullulans Specific Allergen	M203L2	10386021
Immulite 2000 Ulocladium chartarum Specific Allergen	M204L2	10386022
Immulite 2000 Penicillium brevi-compactum Specific Allergen	M305L2	10386030
Immulite 2000 Aspergillus fumigatus Specific Allergen	M3L4	10386036
Immulite 2000 Trichophyton rubrum Specific Allergen	M205L2	10470187