SIEMENS

EU Declaration of Conformity

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

Legal Manufacturer:	Siemens Healthcare Diagnostics 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

2016-08-24

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 Allergy Specific IgG
Catalogue Number (REF):	L2KGG2 L2KGG6
Siemens Material Number (SMN):	10380877 10380880
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Allergy Specific IgG L2KGG
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]

REPUBLICA MOLDOVA «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 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)

REPUBLICA MOLDOVA ... «DIAMEDIX IMPEX» S.R.L. ... SOCIETATEA CU RASPUNDERE LIMITATA

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 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

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 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 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

Date (YYYY-MM-DD) 2016-08-22

«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 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 [YYYY-MM-DD] 2016-08-22

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

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]

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

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
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 1012600019867
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 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. «LAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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 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

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

Date 2017.03.29
[YYYY-MM-DD]

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

EU DECLARATION OF CONFORMITY

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

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 PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L.

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 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

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

REPUBLICA MOLDOVA «DIAMEDIX IMPEX S.R.L.» CENTRU FACTURARE IDNO 1012600019967 SOCIETATEA 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
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 2008-09-24
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIŞINĂU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600016967, SOCIETATEA CU RASPUNDERE LIMITATA

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

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

REPUBLICA MOLDOVA MUN. CHISINAU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012800019367 SOCIETATE CU RASPUNDERE LIMITATA

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 2016-08-22

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

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] 2017-10-03

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

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

2015-03-03

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 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

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

REPUBLICA MOLDOVA PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019961

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 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

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

«DIAMEDIX IMPEX» S.R.L.

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 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] 2016-08-25

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 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]

REPUBLICA MOLDOVA «DIAMEDIX IMPEX» S.R.L. IDNO 1012600...

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

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

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

MOLDOVA PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RASPUNDERE LIMITATA

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 — 2010-08-24

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 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

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

REPUBLICA MOLDOVA PENTRU FACTURA «DIAMEDIX IMPEX» S.R.L. IDNO 1012000019967

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 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

Date (YYYY-MM-DD) 2016-08-24

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]

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 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

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

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

EC 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

2016-08-22

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
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

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 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] 2016-09-26

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 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] 2016-11-16

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 — 2016-06-24

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 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

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

Date: 2016-08-24
[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 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

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 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:

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

2017-07-05

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 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

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

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

2016-08-24

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

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

Date [YYYY-MM-DD] 2019-02-17

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]

REPUBLICA MOLDOVA, mun. CHIŞINĂU, 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 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

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

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 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

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 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

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 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] 2008-12-

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 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

2016-04-21
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

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 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 2015-08-04

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 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

Date [YYYY-MM-DD] 2017-06-14

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 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

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*:

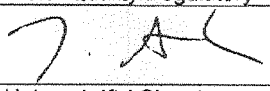
Sonstige	*Others*

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

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

Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 62 Flanders-Bartley Road Flanders, NJ, 07836, USA
Place of Manufacture:	CARCLO TECHNICAL PLASTICS Grant Road Tucson, AZ 85705, USA Hoover Precision Products 1390 Industrial Park Dr., Sault Ste. Marie, MI 49783, USA
EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE 2000 Systems Reaction Tubes
Catalogue Number (REF):	LRXT
Siemens Material Number (SMN):	10385206
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_IMMULITE 2000_RxnTubes
Version:	4.0

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

Signature: Ryan Sherrie

Digitally signed by Ryan Sherrie
DN: serialNumber=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]

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. QA-Los Angeles (Title)

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

SIEMENS

EC 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 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 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