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 AFP
Catalogue Number (REF):	L2KAP2, L2KAP6
Siemens Material Number (SMN):	10381187,10381184
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 AFP
Version:	04

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: 2019.07.22 16:07:59 +01'00'

2019-07-22

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

Date [YYYY-MM-DD]

DIGITAL EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE
0197

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

Legal Manufacturer:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
Place of Manufacture:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE® 2000 Anti-HBs
Catalogue Number (REF):	L2KAH2
Siemens Material Number (SMN):	10381318
Classification:	ANNEX II, List A
Conformity Assessment Route:	ANNEX IV
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
Document Identifier:	EC DEC_IMMULITE® 2000 Anti-HBs
Version:	03

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

Signature: Robak Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF, givenName=Malgorzata, sn=Robak, c=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.08.23 11:49:44 +01'00'

2019-08-23

Malgorzata Robak
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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
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
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:	02

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

Signature: Robak Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.04 14:35:36 Z

2019-02-04

Malgorzata Robak
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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
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE 2000 Anti-TPO Ab
Catalogue Number (REF):	L2KTO2 L2KTO6
Siemens Material Number (SMN):	10381650 10381649
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Anti-TPO Ab L2KTO
Version:	02

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

Signature: Robak Malgorzata

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

2019-02-04

Malgorzata Robak
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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
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
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:	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

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DN: serialNumber=20020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.01.29 12:34:53 Z

2019-01-29

Malgorzata Robak
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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 CMV IgG
Catalogue Number (REF):	L2KCVG2
Siemens Material Number (SMN):	10381309
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 CMV IgG
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: 2019.09.19 15:02:55 +01'00'

2019-09-19

Malgorzata Robak
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Llanberis, Gwynedd, LL55 4EL, UK

Date [YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE
0197

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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 CMV IgM
Catalogue Number (REF):	L2KCM2
Siemens Material Number (SMN):	10381320
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 CMV IgM
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

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DN: serialNumber=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.08.13 16:24:01 +01'00'

2019-08-13

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

Date [YYYY-MM-DD]

SIEMENS

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Place of Manufacture:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE 2000 Free T3
Catalogue Number (REF):	L2KF32 L2KF36
Siemens Material Number (SMN):	10381675 10381682
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Free T3 L2KF3
Version:	02

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

Signature: Robak Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.01.30 22:50:39 Z

2019-01-30

Malgorzata Robak
Regulatory Affairs Supervisor
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Llanberis, Gwynedd LL55 4EL, UK

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
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE 2000 Free T4
Catalogue Number (REF):	L2KFT42 L2KFT46
Siemens Material Number (SMN):	10381678 10381677
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Free T4 L2KFT4
Version:	02

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
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Signature: Robak Malgorzata

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

2019-01-30

Malgorzata Robak
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Llanberis, Gwynedd LL55 4EL, UK

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
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
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:	02

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

Signature: Robak Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.01.31 15:40:57 Z

2019-01-31

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
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]

DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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

Legal Manufacturer:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
Place of Manufacture:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE 2000 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:	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 10:18:47 Z

2019-02-01

Malgorzata Robak
Regulatory Affairs Supervisor
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 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

2019-02-01

Malgorzata Robak
Regulatory Affairs Supervisor
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
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
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:	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 10:17:48 Z

2019-02-01

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
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
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Llanberis, Gwynedd, LL55 4EL, UK

Date [YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

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0197

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Place of Manufacture:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE® 2000 Free PSA
Catalogue Number (REF):	L2KPF2
Siemens Material Number (SMN):	10380984
Classification:	ANNEX II, List B
Conformity Assessment Route:	ANNEX IV
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
Document Identifier:	EC DEC_IMMULITE® 2000 Free PSA
Version:	03

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

Signature: Robak Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z002ONKF, givenName=Malgorzata, sn=Robak, cn=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.09.23 08:50:48 +01'00'

2019-09-23

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

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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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 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:	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

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DN: serialNumber=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.17 22:18:43 Z

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

2019-02-17

Date
[YYYY-MM-DD]

DECLARATION OF CONFORMITY

SIEMENS

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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 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:	02

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Reason: I am approving this document
Date: 2019.02.04 14:34:29 Z

2019-02-04

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
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 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:	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: 2019.03.05 10:27:52 Z

2019-03-05

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
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 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:	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: 2019.03.01 09:46:33 Z

2019-03-01

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

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 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:	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 22:13:33 Z

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

2019-02-17

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*:

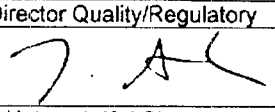
Sonstige	*Others*

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]

SIEMENS

EU Declaration of Conformity

CE

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

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

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

Signature: Robak Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z002CNKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.13 23:32:15 Z

2019-02-13

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

Date [YYYY-MM-DD]