

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product Name: IMMULITE® 2000 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

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Malgorzata Robak
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2019-07-22

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

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Signature:

**Robak
Malgorzata**

**Malgorzata Robak
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Date: 2019.09.26 22:50:36 +01'00'

2019-09-26

**Date
[YYYY-MM-DD]**

DECLARATION OF CONFORMITY

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

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

Product Name: IMMULITE® 2000 Anti-HBs

Catalogue Number (REF): L2KAH2

Siemens Material Number (SMN): 10381318

Classification: ANNEX II, List A

Conformity Assessment Route: ANNEX IV

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nuremberg, Germany
Identification No. 0197

Document Identifier: EC DEC_IMMULITE® 2000 Anti-HBs

Version: 03

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Signature:

Robak Malgorzata

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Malgorzata Robak
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Llanberis, Gwynedd, LL55 4EL, UK

2019-08-23

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

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

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

Signature:

Robak Malgorzata

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DN: serialNumber=200201007, givenName=Malgorzata,
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Reason: I am approving this document
Date: 2019.02.04 14:35:36 Z

2019-02-04

Malgorzata Robak
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Llanberis, Gwynedd LL55 4EL, UK

Date
[YYYY-MM-DD]

DECLARATION OF CONFORMITY

SIEMENS

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Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product 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.*

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Malgorzata

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Reason: I am approving this document
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2019-02-04

Date
[YYYY-MM-DD]

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 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: 02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
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2019-02-01

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product Name: IMMULITE 2000 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:

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Reason: I am approving this document
Date: 2019.01.29 12:34:53 Z

2019-01-29

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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

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:

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Malgorzata

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2019-09-19

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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

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.
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2019-08-13

Date
[YYYY-MM-DD]

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 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.
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o=Siemens, cn=Robak Malgorzata
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Date: 2019.01.30 22:50:39 Z

2019-01-30

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product Name: IMMULITE 2000 Free T4

Catalogue Number (REF): L2KFT42
L2KFT46

Siemens Material Number (SMN): 10381678
10381677

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Free T4 L2KFT4

Version: 02

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

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Date: 2019.01.30 22:40:27 Z

2019-01-30

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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

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.
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Signature:

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Date: 2019.01.31 15:40:57 Z

2019-01-31

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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

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.
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Malgorzata

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Malgorzata Robak
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2019-09-26

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product Name: IMMULITE 2000 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**

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

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Reason: I am approving this document
Date: 2019.02.01 10:18:47 Z

2019-02-01

**Date
[YYYY-MM-DD]**

EU DECLARATION OF CONFORMITY

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
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.
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Signature:

Robak Malgorzata

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

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cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.01 10:21:10 Z

2019-02-01

Date
[YYYY-MM-DD]

DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product Name: IMMULITE 2000 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

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givenName=Malgorzata, sn=Robak, o=Siemens,
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Reason: I am approving this document
Date: 2019.02.01 10:17:48 Z

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

2019-02-01

Date
[YYYY-MM-DD]

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 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.
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Signature:

Robak
Malgorzata

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givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
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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]

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Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product Name: IMMULITE® 2000 Free 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=20020000, givenName=Malgorzata,
sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.09.23 08:50:48 +01'00'

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

2019-09-23

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product Name: IMMULITE 2000 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

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

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DN: serialNumber=20020NKF,
givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.17 22:18:43 Z

2019-02-17

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product Name: IMMULITE 2000 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

*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: 2019.02.04 14:34:29 Z

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

2019-02-04

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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

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=20020NKF,
givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.03.05 10:27:52 Z

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

2019-03-05

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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

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=20020NKF,
givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.03.01 09:46:33 Z

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

2019-03-01

**Date
[YYYY-MM-DD]**

EU DECLARATION OF CONFORMITY



EU Declaration of Conformity



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

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

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

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

2019-02-17

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product Name: IMMULITE 2000 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**

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

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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 23:41:42 Z

2019-02-17

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

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

Product Name: IMMULITE 2000 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: 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

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

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 14:40:00 Z

2019-02-04

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

Konformitätserklärung

Declaration of Conformity



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III erfüllt werden.

We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.

Produktname (deutsch):

IMMULITE 2000 / IMMULITE 2500 Reinigungsmodul

Product name (English):

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):

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2011-04-05

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

Konformitätserklärung

Declaration of Conformity



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III erfüllt werden.

We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.

Produktname (deutsch):

IMMULITE 2000 / IMMULITE 2500 Waschmodul

Product name (English):

IMMULITE 2000 / IMMULITE 2500 Probe Wash Module

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

L2PWSM

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

L2PWSM

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

J. Amborn

Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2011-04-14

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

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 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 Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714**

**Date
[YYYY-MM-DD]**

EU DECLARATION OF CONFORMITY

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 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

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

Digitally signed by Robak Malgorzata
DN: serialNumber=20020N07,
givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.13 23:32:19 Z

2019-02-13

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

Lyphochek Immunoassay Plus Control



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

POCT Methods Listed

Ordering Information

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

Analytes

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

*No claims are made regarding performance or stability.

**Values are not provided.

Did you know . . .

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

Liquichek Tumor Marker Control



- An assayed, multi-analyte control
- Includes low PSA levels for high sensitivity methods and high levels of cancer antigens and Ferritin
- Human based
- 2 year shelf life when stored frozen at -20°C to -70°C
- 30 day open-vial stability at 2-8°C for most analytes

Ordering Information

Cat #	Description
547	Level 1 6 x 2 mL
548	Level 2 6 x 2 mL
549	Level 3 6 x 2 mL
548X	Trilevel MiniPak (1 of each level) 3 x 2 mL



For Dimension Vista® vials, see page 98.

Analytes

Alphafetoprotein (AFP)
 β-2-Microglobulin
 CA 125
 CA 15-3
 CA 19-9
 CA 27.29
 CA 72-4*
 CEA
 Cyfra 21-1*

Ferritin
 hCG
 hCG-β Subunit
 Insulin Growth Factor I (IGF-I)
 PAP
 Prolactin
 PSA
 PSA (Free)
 Thyroglobulin (Tg)

*International Use Only. Not available for diagnostic use in the United States.

Lyphocheck Tumor Marker Plus Control



- A comprehensive, assayed, multi-analyte control
- Ideal for monitoring both routine and esoteric tumor marker testing
- Human serum based
- 14 day reconstituted stability at 2-8°C for most analytes
- 3 year shelf life at 2-8°C

Ordering Information

Cat #	Description
367	Level 1 6 x 2 mL
368	Level 2 6 x 2 mL
369	Level 3 6 x 2 mL
368X	Trilevel MiniPak (1 of each level) 3 x 2 mL

Analytes

β-2-Microglobulin
 ACTH
 Aldosterone
 Alphafetoprotein (AFP)
 CA 15-3
 CA 19-9
 CA 27.29
 CA 50*
 CA 72-4*
 CA 125
 Calcitonin
 CESA*¹

CEA
 Cyfra 21-1*
 Ferritin
 hCG
 hCG-β Subunit
 Neuron Specific Enolase (NSE)*
 PAP
 Prolactin
 PSA
 PSA (Free)
 S-100*
 Thyroglobulin (Tg)

*International Use Only. Not available for diagnostic use in the United States.

¹No claim is made for expected values or stability.

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
Place of Manufacture:	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd, LL55 4EL, UK
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE 2000 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:	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	2019-01-30
	Digitally signed by Robak Malgorzata DN: cn=Robak, o=Siemens, cn=Robak Malgorzata Reason: I am approving this document Date: 2019.01.30 22:10:00 Z	
	Malgorzata Robak Regulatory Affairs Supervisor Siemens Healthcare Diagnostics Products Ltd. Llanberis, Gwynedd LL55 4EL, UK	Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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 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:	02

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

Signature:

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

2019-01-30

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

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

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

2019-02-01

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

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

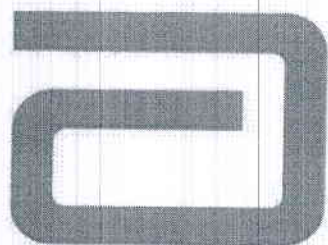
Signature:

Małgorzata Robak
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2019-02-04

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY



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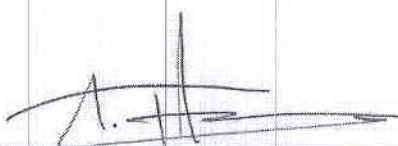
Sergiu Sorocovici

has completed

Architect i2000SR

Level1 / Level 2

Application, Operation, Troubleshooting
from 9 February 2015 to 13 February 2015



Trainer : **Athanasios Plakas**

Date: **13 Feb 2015**



CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Sergiu Sorocovici

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

ARCHITECT c8000 & RSH Service

March 6th – 14th, 2018

Ali Güntekin

TRAINER NAME

ABBOTT DIAGNOSTICS

TRAINER SIGNATURE

14.03.2018

DATE DD.MM.YYYY

Germany - Delkenheim

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