

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 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.*

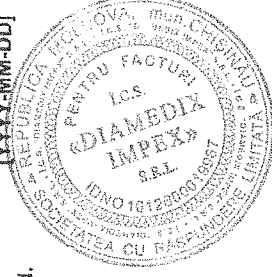
Signature:

Anita Wample

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

Date

20/08/24
[XXX-MM-DD]



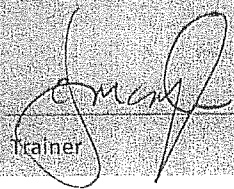
Certificate

Popescu Doru

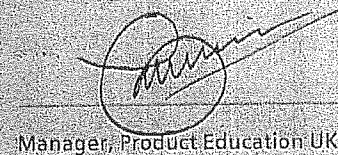
Has successfully completed the following training:

SIEMENS 416-2000/2500 Field Service Training (EMEA)

17/01/2011 to 28/01/2011



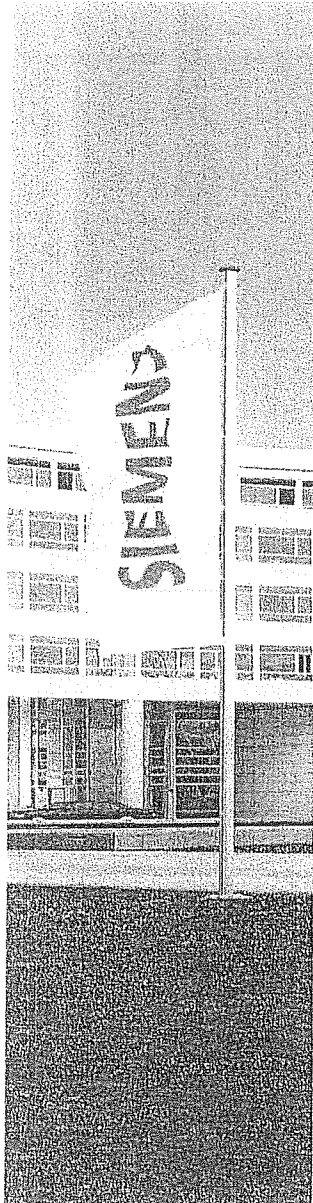
Trainer



Manager, Product Education UK

www.siemens.com/diagnostics

SIEMENS





Certificate

Nechit Romulus

In recognition of your commitment to continuous
learning and professional development
you have completed:

IMMULITE 2000® Application Training Course

from July 13th to July 15th 2009

Aristeidis Kalpias
Instructor

Answers for life.

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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 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

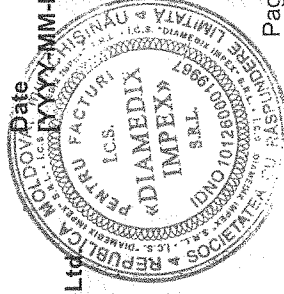
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature: Robak
Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=20020906,
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

Date: 2019-09-25
Signature: Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd
Llanberis, Gwynedd, LL55 4EL, UK



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

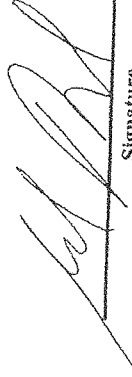
National and other standards and technical specifications:

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

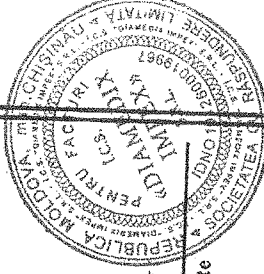
Name/Title of Signatory:

Kamhi Drake

D.C. Drake - Los Angeles

Print Name

Title



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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

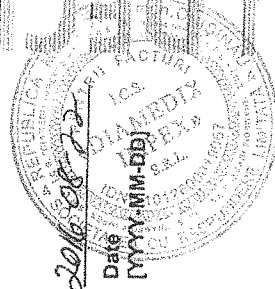
Conformity Assessment Route: ANNEX IV

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



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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):

L2KTZz

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

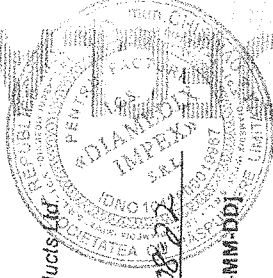
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
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Signature:

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

Date

[YYYY-MM-DD]



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Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
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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): L2KWTW2
L2KWTW6

Siemens Material Number (SMN): 10381190
10381191

Classification: General IVD

Conformity Assessment Route: ANNEX III

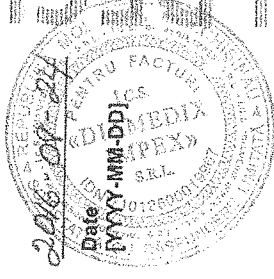
Document Identifier: EC DEC_IMM 2000 Total Testosterone L2KWTW

Version: 01

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



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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

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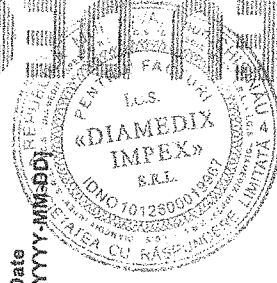
Signature:

Anita Wample

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

Date

20/6/08-2d
07/07/08-0DD



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Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
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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
10381684

Classification: General IVD

Conformity Assessment Route: ANNEX III

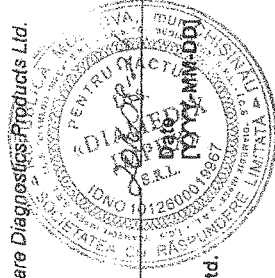
Document Identifier: EC DEC_IMM 2000 Total T4 L2KT4

Version: 01

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

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



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Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 Total 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

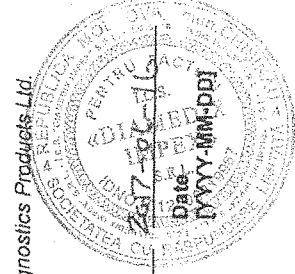
Version:

01

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


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



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 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

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Robak
Malgorzata

Signature:

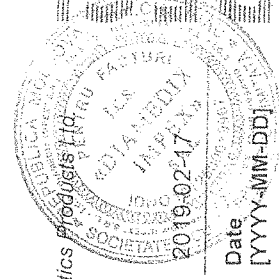
Digitally signed by Robak, Malgorzata
DN: serialNumber=200209NF,
o=Siemens, ou=Robak, cn=Malgorzata

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]



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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

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.
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Signature:

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



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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

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

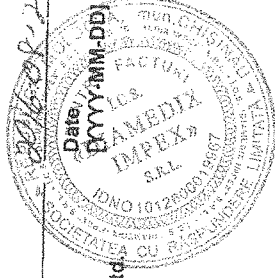
Version:

01

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Signature:

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



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Llanberis, Gwynedd, LL55 4EL, UK

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

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

Product Name: IMMULITE 2000 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

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Digitally signed by Robak Malgorzata
(DN: cn=Robak Malgorzata, o=Siemens, email=robak.malgorzata@siemens.com, c=PL)

Signature: Robak Malgorzata

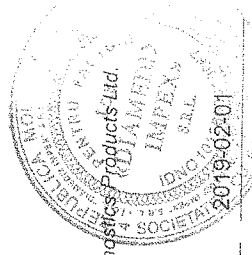
Date: 2019.02.01 10:21:16 Z

Malgorzata 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

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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):

L2KHFG2
L2KHFG6

Siemens Material Number (SMN):

10381336
10381336

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 H. pylori IgG L2KHFG

Version:

01

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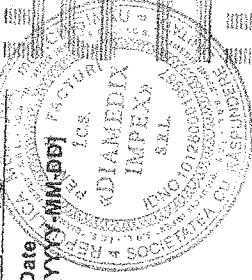
Signature:

Anita Wample

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

Date:

[YYMM-DD] 2016-08-27



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: 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

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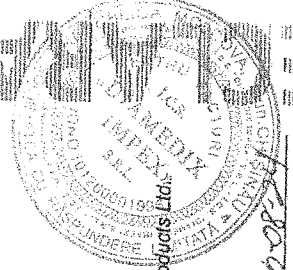
Signature:

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

Date

[YYYY-MM-DD]

2010-08-11



SIEMENS

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Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 Free 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

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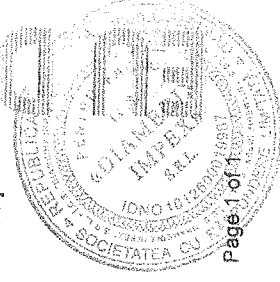
Signature:

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

Date

2016-08-24

[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

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

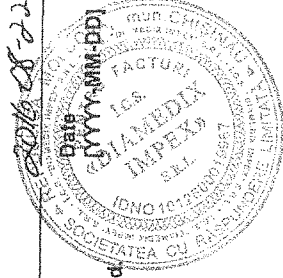
Version: 01

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Signature:

Anita Wample

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



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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

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Signature:

Anita Wample

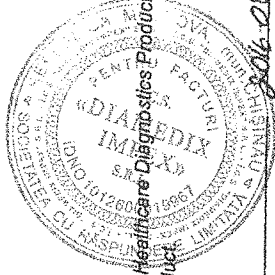
Anita Wample

Head of Quality Management

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

Date

[YYYY-MM-DD]



2006-08-22

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 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

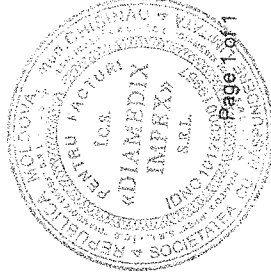
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

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

2016-08-19

Date
[YYYY-MM-DD]



Document No. EC DEC_IMM 2000 CMV IgM L2KCM Ver. 01

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 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.*

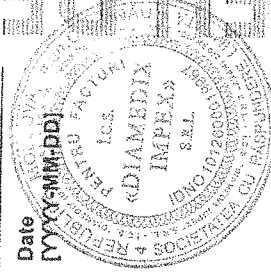
Signature:

Anita Wample

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

Date

2016-05-22
[Signature]



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

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:

Kevin Owen

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



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

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.*

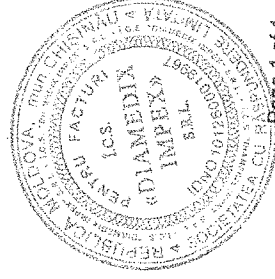
Signature:

Anita Wample
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



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:

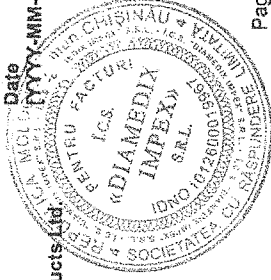
Anita Wample

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

2006-08-24

Date

2006-08-24



SIEMENS

EU Declaration of Conformity



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

Head of Quality Management

Siemens Healthcare Diagnostics Products Ltd.

Llanberis Gwynedd LL55 4EL, UK

2016-08-22

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 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

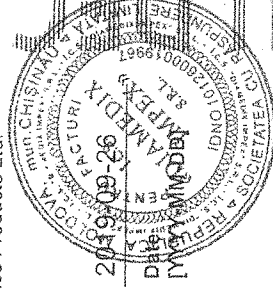
Document Identifier: EC DEC_IMMULITE® 2000 Anti-HBc

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

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



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

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

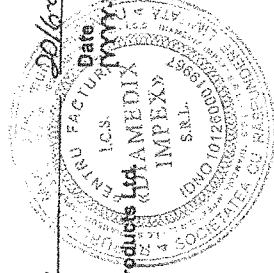
Version: 01

*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 Wamplé

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



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: CARLO 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

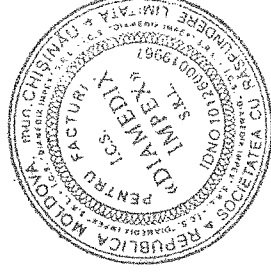
Siemens Material Number (SMN): 10385206

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: DoC_IMMULITE 2000_Rxn Tubes

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=Sherrrie,
sn=Ryan, o=Siemens, cn=Ryan Sherrie
Date: 2019.03.21 09:12:46 -04'00'

Date: [YYYY-MM-DD]
Sherrie Ryan
Sr Manager Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

Konformitätserklärung

Declaration of Conformity



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

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

Produktname (deutsch): IMMULITE 2000 / IMMULITE 2500 Waschmodul

Product name (English): IMMULITE 2000 / IMMULITE 2500 Probe Wash Module

Produkt-Nr. / Product No. (REF): L2PWSM

Packungsgröße(n) / Package Size(s) (REF): L2PWSM

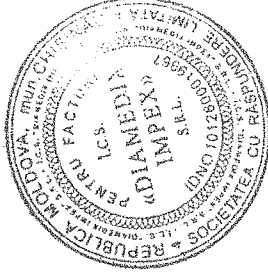
IVD-Kategorie / IVD Category: Sonstige Others

Hersteller / Manufacturer: Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland): Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg

Address (international): Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Bestätigung / Authorization: Director Quality/Regulatory	
Unterschrift / Signature	
Dr. Jörg Amborn	
Name /Name	
2011-04-14	
Datum [JJJ-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 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: L2KPM

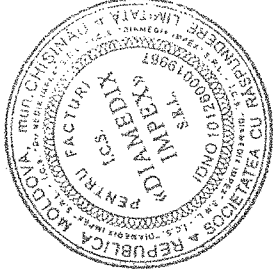
Sonstige: Others

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]:



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 Thlrld 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 Thlrld 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.*

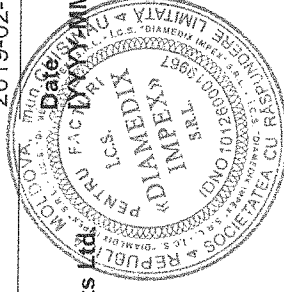
Robak
Malgorzata
Digitally signed by Robak Malgorzata
DN: serialNumber=20020NKF,
givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
Reason: I am approving this document.
Date: 2019.02.17 22:13:33 Z

Signature:

Robak
Malgorzata

2019-02-17

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



SIEMENS

EU Declaration of Conformity



0088

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

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

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

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

Product Name: IMMULITE 2000 HBsAg

Catalogue Number (REF): L2KHB2

Siemens Material Number (SMN): 10381306

Classification: ANNEX II, List A

Conformity Assessment Route: ANNEX IV

Notified Body: Lloyd's Register Quality Assurance Ltd.
1 Trinity Park, Bickenhill Lane
Solihull, B37 7ES, UK
Identification No. 0088

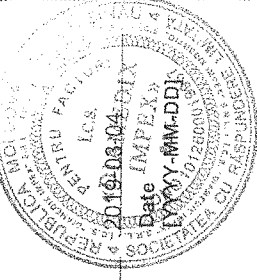
Document Identifier: EC DEC_IMM 2000 HBsAg L2KHB

Version: 02

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

Signature: Robak
Malgorzata

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



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

Product Name:

IMMULITE 2000 Free T4

Catalogue Number (REF):

L2KFT42
L2KFT46

Siemens Material Number (SIMN):

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

2016-08-27

Date

MOLDOVA

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Page 1 of 1

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

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.*

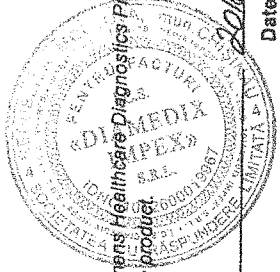
Signature:

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

Date

[YYYY-MM-DD]

2016-08-22



EU DECLARATION OF CONFORMITY