

SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 3g Allergy Specific IgE Universal Kit

Catalogue Number (REF):

L2KUN6

Siemens Material Number (SMN):

10380875

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 3g Allergy Specific IgE Universal Kit L2KUN

Version:

01

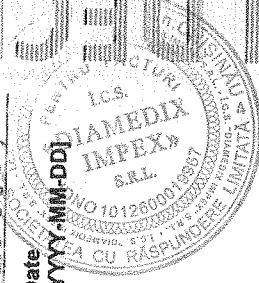
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

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

Date
[YYMM-MM-DD]

2006-08-24





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.

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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 Allergy Specific IgG

Catalogue Number (REF):

L2KGG2

L2KGG6

Siemens Material Number (SMN):

10380877

10380880

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Allergy Specific IgG L2KGG

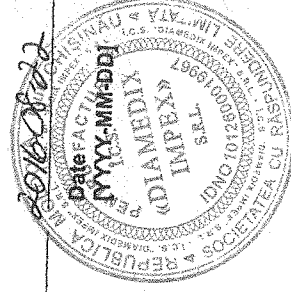
Version:

01

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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 ACTH

Catalogue Number (REF): L2KAC2

Siemens Material Number (SMN): 10381468

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 ACTH L2KAC

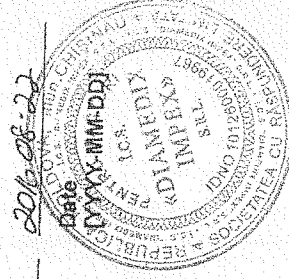
Version: 01

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Anita Wample

Anita Wample
Head of Quality Management
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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

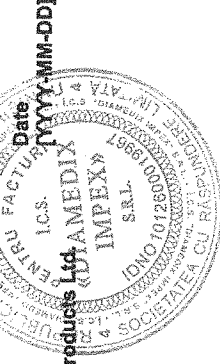
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Signature:

Anita Wamplé

20/6/22

Anita Wamplé
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 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

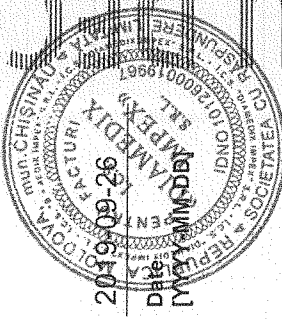
Version: 03

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
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Digitally signed by Robak Malgorzata
DN: serialNumber=200209NF,
givenName=Malgorzata, sn=Robak,
o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.09.26 22:50:36 +01'00'

Signature: Robak
Malgorzata

Malgorzata Robak
Regulatory Affairs Supervisor
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 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

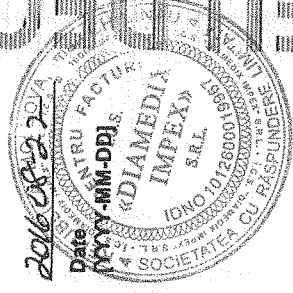
Document Identifier: EC DEC_IMM 2000 Anti-HBs L2KAH

Version: 01

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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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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

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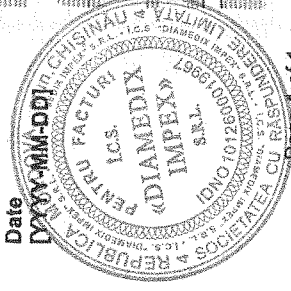
Signature:

Anita Wample

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

Date

2016-08-22



SIEMENS

EU Declaration of Conformity



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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 Anti-TPO Ab

Catalogue Number (REF): L2KTO2
L2KTO6

Siemens Material Number (SMN): 10381650
10381649

Classification: General IVD

Conformity Assessment Route: ANNEX III

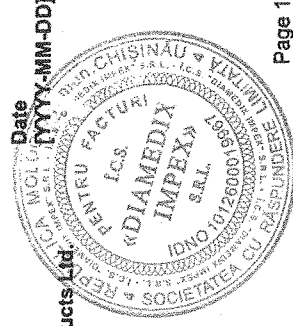
Document Identifier: EC DEC_IMM 2000 Anti-TPO Ab L2KTO

Version: 01

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Signature: *Anita Wample* _____ *2006-08-24*

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



EU Declaration of Conformity



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Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 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

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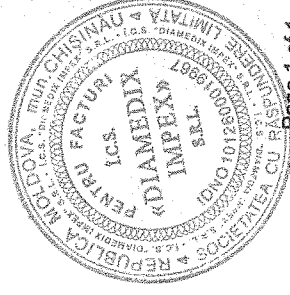
Signature:

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

Date

[YYYY-MM-DD]

2016-08-22



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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 Calcitonin

Catalogue Number (REF): L2KCL2

Siemens Material Number (SMN): 10381446

Classification: General IVD

Conformity Assessment Route: ANNEX III

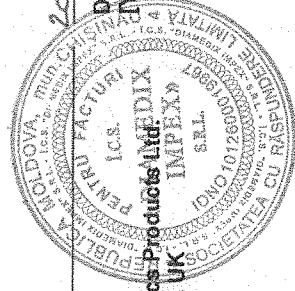
Document Identifier: EC DEC_IMM 2000 Calcitonin L2KCL

Version: 01

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Signature:

Kevin Owen
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 CEA

Catalogue Number (REF):

L2KCE2
L2KCE6

Siemens Material Number (SMN):

10380994
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Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 CEA L2KCE

Version:

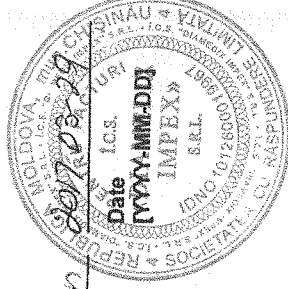
01

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Signature:

Kevin Owen

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



EU DECLARATION OF CONFORMITY

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We hereby declare that the product described below conforms to all applicable requirements of Council Directive 93/79/EEC 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

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Signature:

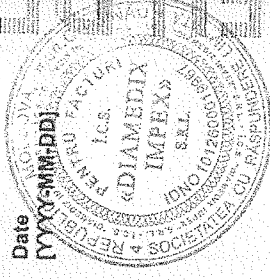
Anita Wample

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

2016-08-22

Date

[MXX-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 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

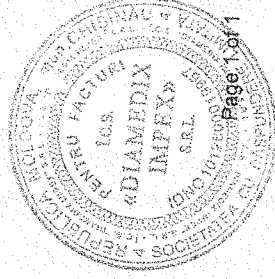
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Anita Wample
Head of Quality Management
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Llanberis Gwynedd LL55 4EL, UK

2016-08-19

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 Cortisol

Catalogue Number (REF): L2KCO2
L2KCO6

Siemens Material Number (SMN): 10381476
10381480

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Cortisol L2KCO

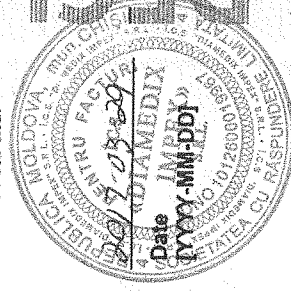
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Kevin Owen

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



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

Product Name: IMMULITE 2000 C-Peptide

Catalogue Number (REF): L2KPEP2

Siemens Material Number (SMN): 10381450

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 C-Peptide L2KPEP

Version: 01

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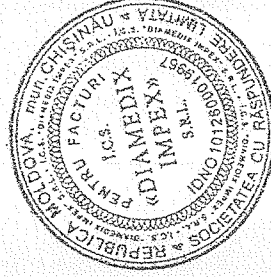
Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
Llanberis Gwynedd LL55 4EL, UK

Date
[YYYY-MM-DD]

20th Dec 2024

Document No. EC DEC_IMM 2000 C-Peptide L2KPEP Ver. 01

Page 1 of 1



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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 D-Dimer

Catalogue Number (REF): L2KDD2

Siemens Material Number (SMN): 10381041

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 D-Dimer L2KDD

Version: 01

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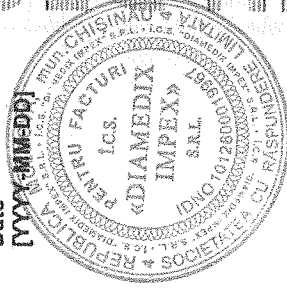
Anita Wample

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

Date

[YYYY-MM-DD]

20/08/24



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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 DHEA-SO4

Catalogue Number (REF):

L2KDS2

Siemens Material Number (SMN):

10381193

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 DHEA-SO4 L2KDS

Version:

01

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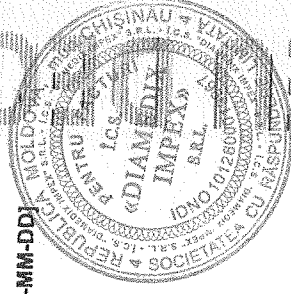
Anita Wample

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

Date

[YYYY-MM-DD]

2016-08-22



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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 EBV-EBNA IgG

Catalogue Number (REF):

L2KEB2

Siemens Material Number (SMN):

10381307

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

EC DOC_IMM2000 EBV-EBNA IgG L2KEB

Version:

01

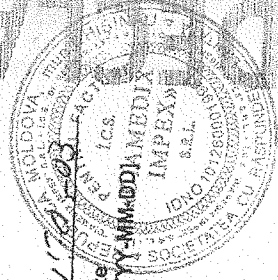
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Signature:

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

Date:

17/07/2003



SIEMENS

EC Declaration of Conformity



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Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 EBV-VCA IgG

Catalogue Number (REF):

L2KVG2

Siemens Material Number (SMN):

10381330

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

EC DEC_IMM2000 EBV-VCA IgG L2KVG

Version:

01

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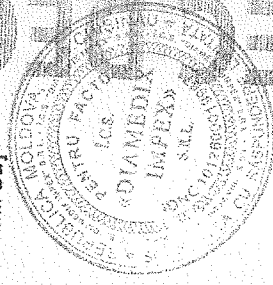
Signature:

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

Date

[YYYY-MM-DD]

2015-03-03



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

Signature:

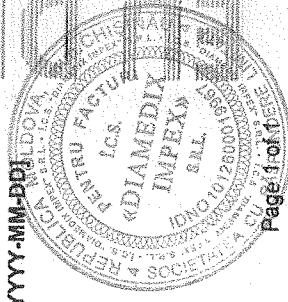
Anita Wample

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

Date

[YYYY-MM-DD]

2016-08-22



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 Ferritin

Catalogue Number (REF):

L2KFE2
L2KFE6

Siemens Material Number (SMN):

10380908
10380906

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Ferritin L2KFE

Version:

01

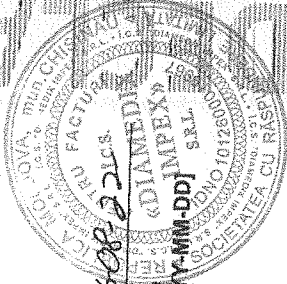
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Anita Wample

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

Date
20/08/2015
[MM-YY-DD]



EU Declaration of Conformity



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Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 Folic Acid

Catalogue Number (REF):

L2KFO2
L2KFO6

Siemens Material Number (SMN):

10380911
10380912

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Folic Acid L2KFO

Version:

01

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

Signature:

Anita Wample

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

Date

[YYYY-MM-DD]



EU Declaration of Conformity



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Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 Free Beta HCG

Catalogue Number (REF):

L2KFB2

Siemens Material Number (SMN):

10381175

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Free Beta HCG L2KFB

Version:

01

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Signature:

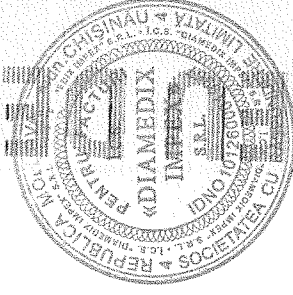
Anita Wample

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

Date

[YYYY-MM-DD]

2016-08-22



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/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

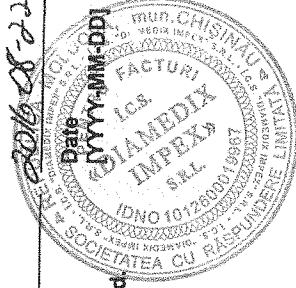
Version:

01

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Signature:

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



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 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:

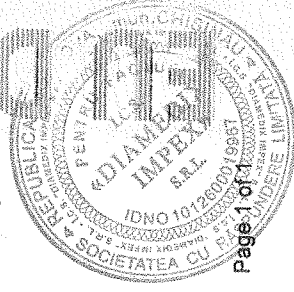
Anita Wample

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

Date

[YYYY-MM-DD]

2016-08-24



SIEMENS

EU Declaration of Conformity



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

Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 Free T4

Catalogue Number (REF):

L2KFT42

L2KFT46

Siemens Material Number (SMN):

10381678

10381677

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Free T4 L2KFT4

Version:

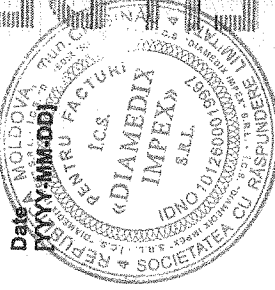
01

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

Signature:

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

Date: 26/08/22



EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 FSH

Catalogue Number (REF):

L2KFS2
L2KFS6

Siemens Material Number (SMN):

10381201
10381180

Classification:

General IMD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 FSH L2KFS

Version:

01

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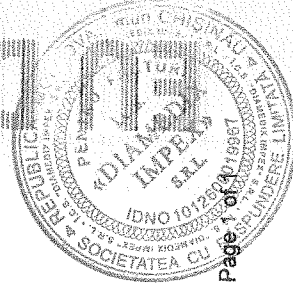
Signature:

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

Date

[YYYY-MM-DD]

2010-08-24



Page 1 of 1

Document No. EC DEC_IMM 2000 FSH L2KFS Ver. 01

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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 GI-MA

Catalogue Number (REF):

L2KG12

Siemens Material Number (SMN):

10380988

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 GI-MA L2KG1

Version:

01

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

Signature:

Anita Wample

Anita Wample

Head of Quality Management

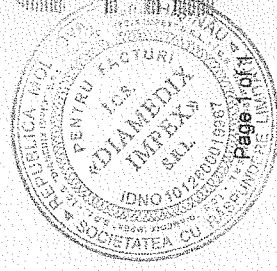
Siemens Healthcare Diagnostics Products Ltd.

Llanberis Gwynedd LL55 4EL, UK

Date

[YYYY-MM-DD]

2016-08-24



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 Growth Hormone (hGH)

Catalogue Number (REF):

L2KGRH2

Siemens Material Number (SMN):

10381451

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Growth Hormone (hGH) L2KGRH

Version:

01

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Signature:

Anita Wample

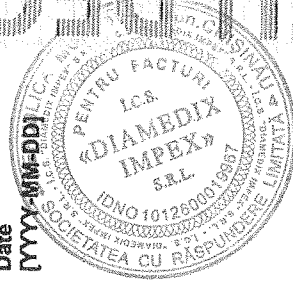
Anita Wample

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

Date

[YYYY-MM-DD]

2016-08-24



EU DECLARATION OF CONFORMITY

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

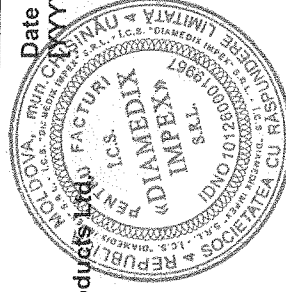
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Digitally signed by Robak Malgorzata
DN: serialNumber=200209NF,
givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.09.26 22:54:24 +01'00'

**Robak
Malgorzata**

Date
2019-09-26

**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 HCG

Catalogue Number (REF):

L2KCG2
L2KCG6

Siemens Material Number (SMN):

10381206
10381194

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 HCG L2KCG

Version:

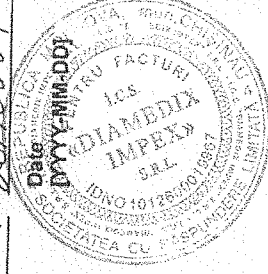
01

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

Signature:

Kevin Owen 201703-29

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



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

Product Name:

IMMULITE 2000 H. pylori IgG

Catalogue Number (REF):

L2KHPG2
L2KHPG6

Siemens Material Number (SMN):

10381336
10381335

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 H. pylori IgG L2KHPG

Version:

01

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

Signature:

Anita Wamplé

Anita Wamplé

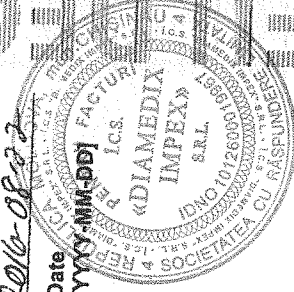
Head of Quality Management

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

Date

[YYMM-PP]

2016-08-22



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 Herpes I & II IgG

Catalogue Number (REF): L2KHVVG6

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

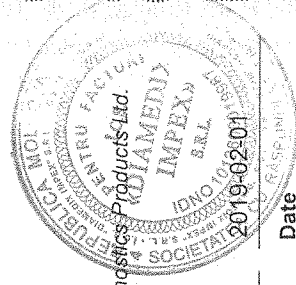
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Digitally signed by Robak Malgorzata
DN: surname=20220607,
cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.01 10:21:10 Z

Signature: Robak Malgorzata

**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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Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 Homocysteine

Catalogue Number (REF):

L2KHO2

Siemens Material Number (SMN):

10381040

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Homocysteine L2KHO

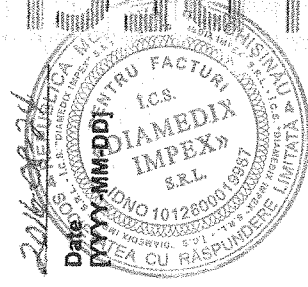
Version:

01

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Signature:

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



EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 Insulin

Catalogue Number (REF):

L2KIN2
L2KIN6

Siemens Material Number (SMN):

10381455
10381456

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Insulin L2KIN

Version:

01

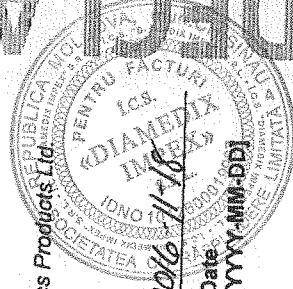
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
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Signature:

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

Date

2016-11-18
[YY-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

Product Name:

IMMULITE 2000 Intact PTH

Catalogue Number (REF):

L2KPP2
L2KPP6

Siemens Material Number (SMN):

10381441
10381442

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Intact PTH L2KPP

Version:

01

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

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

Date

[YYYY-MM-DD]

2016-08-24

Document No. EC DEC_IMM 2000 Intact PTH L2KPP Ver. 01

Page 1 of 1



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 LH

Catalogue Number (REF):

L2KLH2
L2KLH6

Siemens Material Number (SIMN):

10381211
10381212

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 LH L2KLH

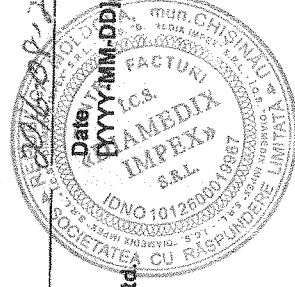
Version:

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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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

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

Signature:

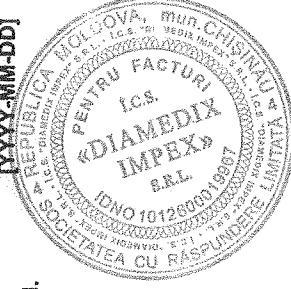
20/08/24

Anita Wample

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

Date
2024-08-24

[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

Product Name:

IMMULITE 2000 Osteocalcin

Catalogue Number (REF):

L2KON2

Siemens Material Number (SMN):

10381477

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:


EC DEC_IMM 2000 Osteocalcin L2KON

Version:

01

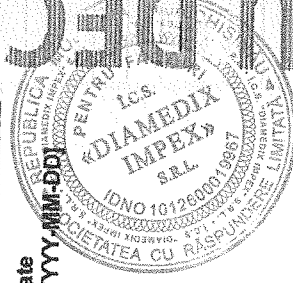
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature:


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

Date
[YYYY-MM-DD]

2017-07-05



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 PAPP-A

Catalogue Number (REF): L2KPC2

Siemens Material Number (SMN): 10381213

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 PAPP-A L2KPC

Version: 01

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

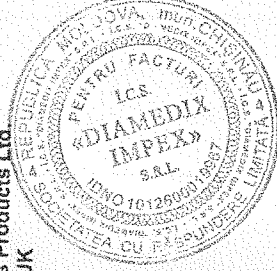
Signature:

Anita Wamplé

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

Date
[YYYY-MM-DD]

20/09/24



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 Progesterone

Catalogue Number (REF): L2KPW2
L2KPW6

Siemens Material Number (SMN): 10381181
10381170

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Progesterone L2KPW

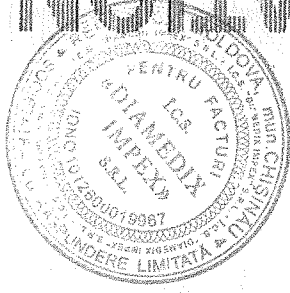
Version: 01

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

Signature:

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

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

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.*

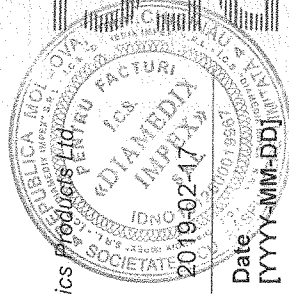
Robak

Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF,
o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.17 23:41:42 Z

Signature:

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



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 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

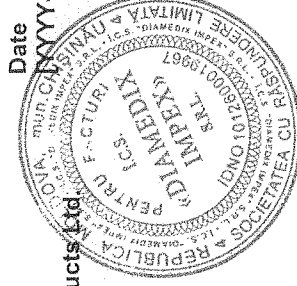
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Digitally signed by Robak Malgorzata
DN: serialNumber=20020NFC,
o=Robak Malgorzata, ou=Siemens,
Reason: I am approving this document
Date: 2019.09.25 09:58:23 +01'00'

Signature: Robak
Malgorzata

Date: 2019-09-25

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 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 Pylinks-D

Catalogue Number (REF):

L2KPD2

Siemens Material Number (SMN):

10381461

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Pylinks-D L2KPD

Version:

01

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

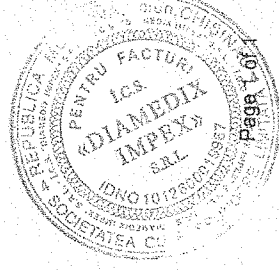
Signature:

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

Date

[YYYY-MM-DD]

2016-08-20



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 Thyroglobulin

Catalogue Number (REF):

L2KTY2

Siemens Material Number (SMN):

10381648

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Thyroglobulin L2KTY

Version:

01

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

Signature:

Anita Wample

Anita Wample

Head of Quality Management

Siemens Healthcare Diagnostics Products Ltd.

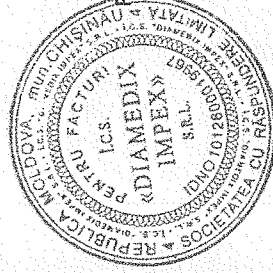
Llanberis Gwynedd LL55 4EL, UK

Date

[YYYY-MM-DD]

2016-08-26

Document No. EC DEC_IMM 2000 Thyroglobulin L2KTY Ver. 01



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 Total IgE

Catalogue Number (REF):

L2KIE2
L2KIE6

Siemens Material Number (SMN):

10380873
10380872

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:


EC DEC_IMM 2000 Total IgE L2KIE

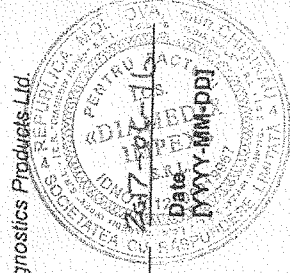
Version:

01

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

Signature:


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



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

Product Name: IMMULITE 2000 Total T3

Catalogue Number (REF): L2KT32
L2KT36

Siemens Material Number (SMN): 10381654
10381657

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Total T3 L2KT3

Version: 01

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

Signature:

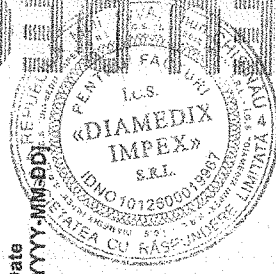
Anita Wample

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

Date

[YYYY-MM-DD]

2016-08-20



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 Total T4

Catalogue Number (REF): L2KT42
L2KT46

Siemens Material Number (SMN): 10381685
10381664

Classification: General IVD

Conformity Assessment Route: ANNEX III

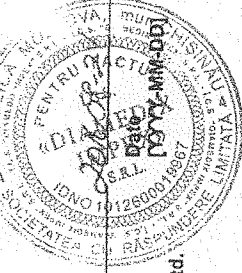
Document Identifier: EC DEC_IMM 2000 Total T4 L2KT4

Version: 01

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

Signature:

Anita Wample
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 products described below conform to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:

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

Place of Manufacture:

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

Product Name:

IMMULITE 2000 Total Testosterone

Catalogue Number (REF):

L2KTW2
L2KTW6

Siemens Material Number (SMN):

10381190
10381191

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Total Testosterone L2KTW

Version:

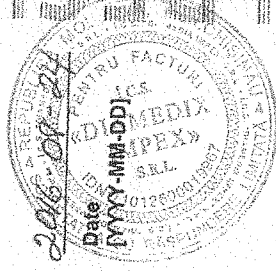
01

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

Signature:

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

Signature:

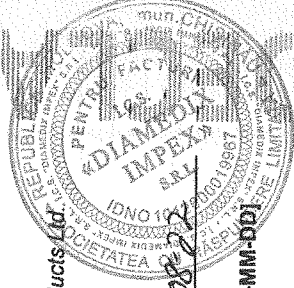
Anita Wample

Head of Quality Management

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

Date

[YYYY-MM-DD]



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 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

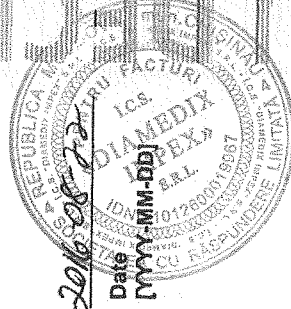
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

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

Date

2016-08-22



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 Third Generation TSH

Catalogue Number (REF):

L2KTS2
L2KTS6

Siemens Material Number (SMN):

10381665
10381667

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Third Generation TSH L2KTS

Version:

01

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

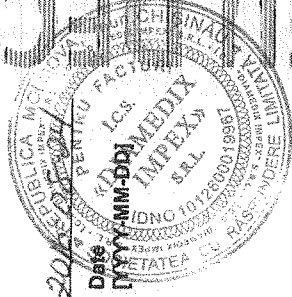
Signature:

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

Date:

20/05/2004

0000-0000-0000



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 Unconjugated Estriol (UE3)

Catalogue Number (REF):

L2KUE32
L2KUE36

Siemens Material Number (SMN):

10381192
10381171

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Unconjugated Estriol L2KUE3

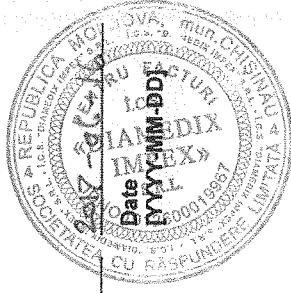
Version:

01

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

Signature:

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



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

Product Name: IMMULITE 2000 Vitamin B12

Catalogue Number (REF): L2KV/B2
L2KV/B6

Siemens Material Number (SMN): 10380914
10380913

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC_DEC_IMM 2000 Vitamin B12 L2KV/B

Version: 01

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

Signature:

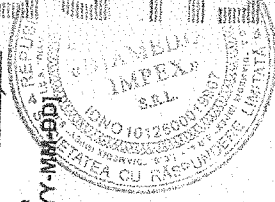
Anita Wample

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

Date

[YYYY-MM-DD]

2016-08-24



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

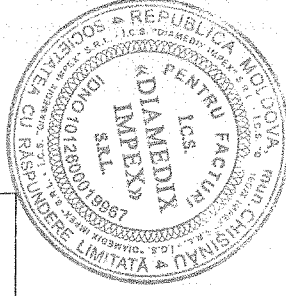
Unterschrift / Signature

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=Z00262FR, 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

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

Manufacturer:

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

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

Device type:

In Vitro Diagnostic Medical Device

Device name:

IMMULITE® 2000 Chemiluminescent Substrate

Catalog number:

L2SUBM

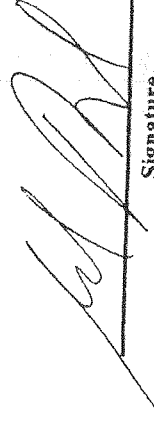
National and other standards and technical specifications:

EN 375, EN 980, ISO 13485, EN 13612, EN 13640, EN 13641, ISO 14971, ISO/IEC 17050-1, 2, EN 17511, 21 CFR 820

EU Representative:

**Siemens Healthcare Diagnostics Limited
Faraday House
Sir William Siemens Square, Frimley
Camberley, GU16 8QD
United Kingdom**

Signature/Date of Manufacturer or Responsible Party:



Signature

08/17/09

Date

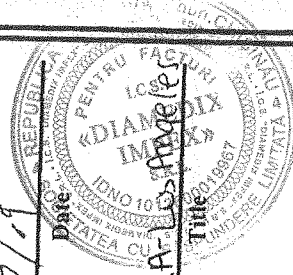
Name/Title of Signatory:

Kambiz Drake

Print Name

D.O. Drake

Title



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 AlaTOP

Catalogue Number (REF):

L2KAT2

Siemens Material Number (SMN):

10380878

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 AlaTOP L2KAT

Version:

01

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

Signature:

Anita Wample

Anita Wample

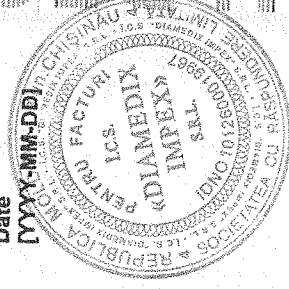
Head of Quality Management

Siemens Healthcare Diagnostics Products Ltd.

Llanberis Gwynedd LL55 4EL, UK

Date

2016-08-22



SIEMENS

EC 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 EBV-VCA IgM

Catalogue Number (REF):

L2KEM2

Siemens Material Number (SMN):

10488005

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

EC DEC_IMM2000 EBV-VCA IgM L2KEM

Version:

01

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

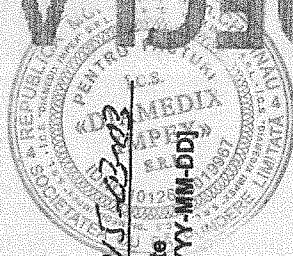
Signature:

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

Date

[YYYY-MM-DD]

2015-03-03



EC DECLARATION OF CONFORMITY