

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

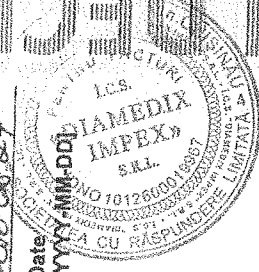
Siemens Healthcare Diagnostics Products Ltd.

Llanberis Gwynedd LL55 4EL, UK

Date:

17/03/2004

2006-08-24



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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

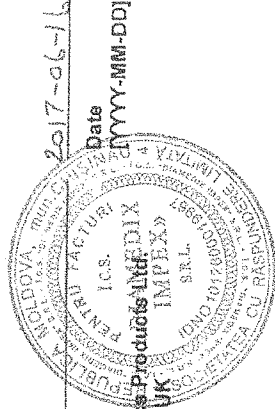
Version:

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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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

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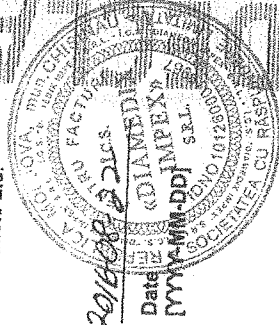
Signature:

Anita Wample

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

Date

20/08/2015
[YYMMDD]



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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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Signature:

Anita Wample

Anita Wample

Head of Quality Management

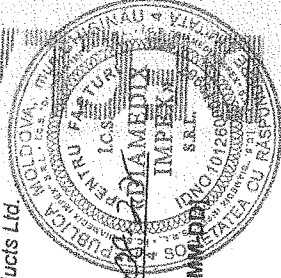
Siemens Healthcare Diagnostics Products Ltd.

Llanberis Gwynedd LL55 4EL, UK

2006-08-28

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

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:

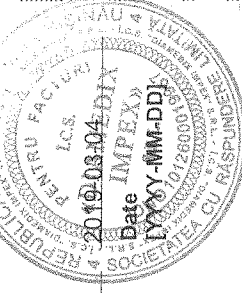
EC DEC_IMM 2000 HBsAg L2KHB

Version:

02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
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Digitally signed by Robak Malgorzata,
DN: cn=Robak Malgorzata,
o=Siemens,
ou=Malgorzata, email=malgorzata.malgorzata@siemens.com,
c=PL



Signature:

Robak
Malgorzata
Malgorzata Robak
Regulatory Affairs Supervisor
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 Intact PTH

Catalogue Number (REF):

L2KPP2
L2KPP6

Siemens Material Number (SMN):

10381441
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Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

EC DEC_IMM 2000 Intact PTH L2KPP

Version:

01

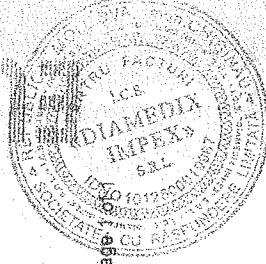
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Signature:

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

Date

[YYYY-MM-DD]



DECLARATION OF CONFORMITY

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 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

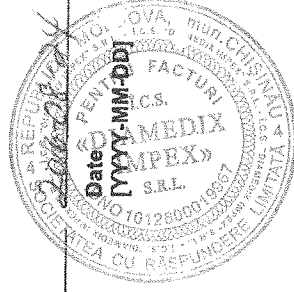
Version:

01

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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

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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 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

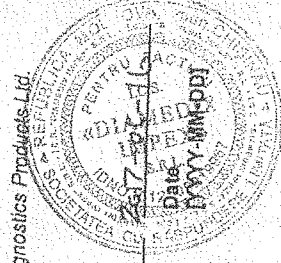
Version:

01

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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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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

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Signature:

Anita Wample

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

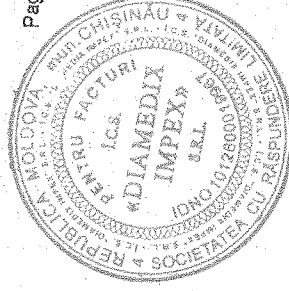
Date

[YYYY-MM-DD]

2016-08-24



Document No. EC DEC_IMM 2000 Vitamin B12 L2KV/B Ver. 01



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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

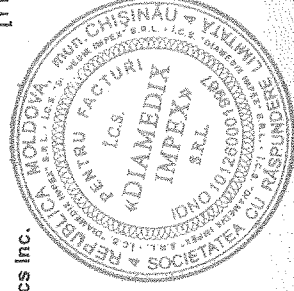
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
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Ryan Sherrie

Digitally signed by Ryan Sherrie
DN: serialNumber=200262FR, givenName=Sherrie,
sn=Ryan, o=Siemens, cn=Ryan Sherrie
Date: 2019.05.21 09:12:46 -04'00'

Signature:

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



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

Manufacturer:

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

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

Device type:

In Vitro Diagnostic Medical Device

Device name:

IMMULITE® 2000 Chemiluminescent Substrate

Catalog number:

L2SUBM

National and other standards and technical specifications:

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

EU Representative:

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

**Signature/Date of
Manufacturer or
Responsible Party:**

[Handwritten Signature]
Signature

08/17/09

Name/Title of Signatory:

Kambiz Drok
Print Name

D.R. DROK

