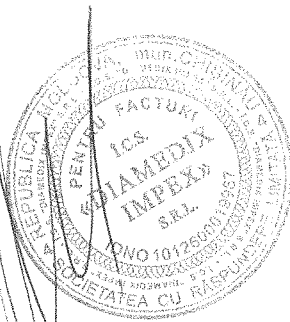


**Catre: IMSP Centrul Republican de Diagnosticare Medicala**

mun.Chişinău, str. C. Virnav 13

Prin prezenta, **ICS Diamedix SRL** confirma ca, termenul de valabilitate a reactivilor e 12 luni cu exceptia celor specificate de producator.

Data: 04.09.2019  
Administrator  
Traian Marinescu

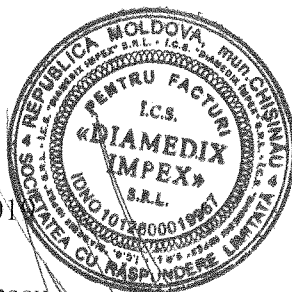


**Catre: IMSP Centrul Republican de Diagnosticare Medicala**

mun.Chişinău, str. C. Virnav 13

Prin prezenta, **ICS Diamedix SRL** confirma ca, este distribuitor autorizat de catre **SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS** in Republica Moldova (autorizatie in anexa) si ca toate produsele propuse sint achizitionate de la acest producator. Prin urmare produsele sint compatibile cu echipamentul beneficiarului Immulite 2000 Siemens si garantam prin asumarea de raspundere financiara deplina in cazul defectiunilor produse echipamentului de calitate insuficienta a reagentilor si consumabilelor.

Data: 04.09.201  
Administrator  
Traiam Marinescu



Siemens Healthcare Diagnostics Products GmbH, Marburg, Germany

To whom it may concern  
For presentation in  
the Republic of Moldova

Name	Tobias Thäns
Department	HC LC LD
Telephone	+49 (6196) 7713-2414
Fax	+49 (6196) 7713-7007
E-Mail	tobias.thaens@siemens-healthcare.com
Our reference	18-0059
Date	June 11, 2018

**MANUFACTURER'S AUTHORIZATION**

SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS GMBH a company incorporated and existing under the laws of the Federal Republic of Germany, with offices located at Emil-von-Behring-Strasse 76, 35041 Marburg, Germany (the "Company"), hereby acknowledges that it has designated ICS Diamedix Impex SRL, a company incorporated in the Republic of Moldova under the fiscal code (IDNO) 1012600019967 ("Representative") as an AUTHORIZED REPRESENTATIVE for the Republic of Moldova. As such Representative is duly authorized to register and re-register the Siemens Healthineers in-vitro products (the "Products"). The manufacturing facilities of the Company and its affiliates are listed in Attachment A.

In accordance with an Authorized Representative Agreement dated November 23, 2015, Siemens will, among other things, provide to the Representative such product-related technical documentation relevant to market surveillance investigations being undertaken by the Medicines and Medical Devices Agency in the Territory as may reasonably be required. In connection with the requirements of Annex 3 to the Administrative Procedures for Registration of medical devices nr. AG/PS-01Rg04-112 dated 03.07.2014, however, we point out that the following information relating to the Products, to the extent not disclosed in documentation accompanying the Products (such as Instructions for Use) concerns trade secrets and/or binding confidentiality obligations:

3. Information on design and manufacturing
4. General requirements on safety and performance
5. Risk-benefit analysis and risk management
6. Verification and validation of product.

This Manufacturer's Authorization does not confer any powers or authorizations beyond those contained herein. The present authorization should not be interpreted as an extension or renewal of any Authorized Representative Agreement or other contractual relationship. This letter of authorization shall remain valid until the process of registration ends or for 1 year from the date of this letter, whichever comes later, unless revoked sooner by the Company.

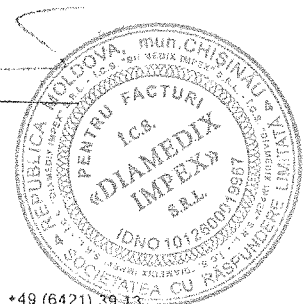
On behalf of Siemens Healthcare Diagnostics Products GmbH



Name: Michael Heinold  
Title: Managing Director



Name: Jörg Berner  
Title: Managing Director



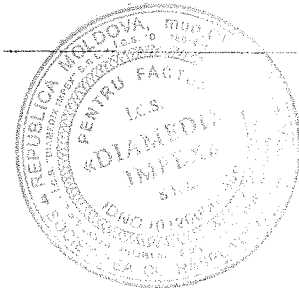
Siemens Healthcare Diagnostics Products GmbH  
Management: Michael Heinold, Joerg Berner, Tobias Thaens

Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Tel.: +49 (6421) 39 43

Attachment A- List of Affiliates and Manufacturing Facilities:

Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591-5097 USA	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin Ireland
Siemens Healthcare Diagnostics Manufacturing Ltd. Northern Road Chilton Industrial Estate Sudbury, Suffolk CO 10 2XQ United Kingdom	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd LL55 4EL United Kingdom
Siemens Healthcare Diagnostics Inc. 2 Edgewater Drive Norwood, MA 02062-4658 USA	Siemens Healthcare Diagnostics Inc. 3400 Middlebury Street Elkhart, IN 46516 USA
Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA 02032 USA	Siemens Healthcare Diagnostics Inc. 62 Flanders-Bartley Road Flanders, NJ 07836 USA
Siemens Healthcare Diagnostics Inc. 725 Potter Street Berkeley, CA 94710 USA	Siemens Healthcare Diagnostics Inc. 5210 Pacific Concourse Drive Los Angeles, CA 90045-6900 USA
Siemens Healthcare Diagnostics Inc. 115 Norwood Park South Norwood, MA 02062 USA	Siemens Healthcare Diagnostics Inc. 45764 Copco Avenue Gorman, California 93243 USA
Siemens Healthcare Diagnostics Inc. 500 GBC Dr., Mailstop 514 P.O. Box 6101 Newark, DE 19714 USA	Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Strasse 76 35041 Marburg Germany
Siemens Healthcare Diagnostics Inc. 430 S. Beiger Street Mishawaka, Indiana 46544 USA	Siemens Healthcare Diagnostics Inc. 101 Silvermine Road Brookfield, CT 06804 USA



## 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  
2016-08-22  
[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 LH

**Catalogue Number (REF):** L2KLH2  
L2KLH6

**Siemens Material Number (SMN):** 10381211  
10381212

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

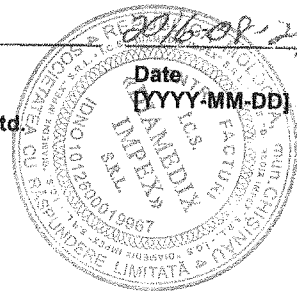
**Document Identifier:** EC DEC\_IMM 2000 LH L2KLH

**Version:** 01

*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



# 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 Insulin

**Catalogue Number (REF):** L2KIN2  
L2KIN6

**Siemens Material Number (SMN):** 10381455  
10381456

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

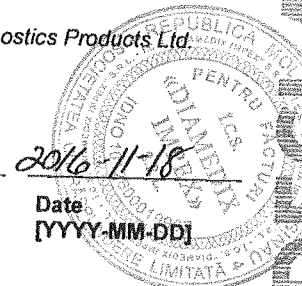
**Document Identifier:** EC DEC\_IMM 2000 Insulin L2KIN

**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  
[YYYY-MM-DD]

EU 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 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

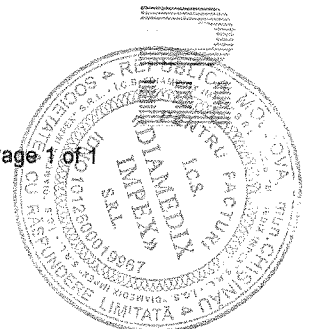
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
This declaration supersedes any declaration issued previously for the same product.*

**Signature:**

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

2016-08-24

Date  
[YYYY-MM-DD]





# 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 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

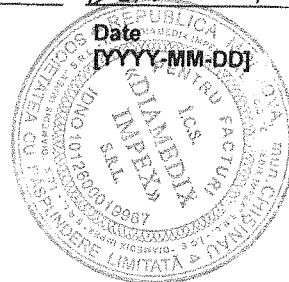
**Version:** 01

*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

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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 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

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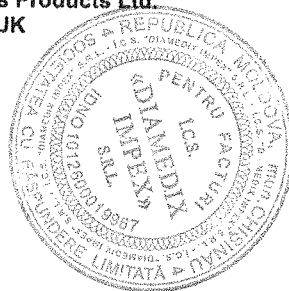
**Signature:**

*Anita Wample*

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

*2016-09-24*

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 Progesterone

**Catalogue Number (REF):** L2KPW2  
L2KPW6

**Siemens Material Number (SMN):** 10381181  
10381170

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

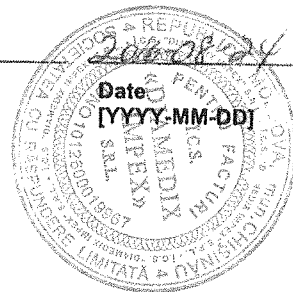
**Document Identifier:** EC DEC\_IMM 2000 Progesterone L2KPW

**Version:** 01

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**Signature:**

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



# SIEMENS

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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 Total IgE

**Catalogue Number (REF):** L2KIE2  
L2KIE6

**Siemens Material Number (SMN):** 10380873  
10380872

**Classification:** General IVD


**Conformity Assessment Route:** ANNEX III

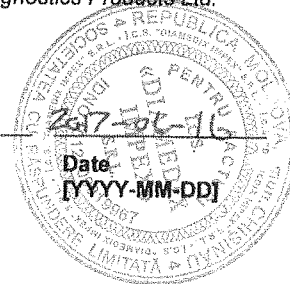
**Document Identifier:** EC DEC\_IMM 2000 Total IgE L2KIE

**Version:** 01

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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

## 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 Total T3

**Catalogue Number (REF):** L2KT32  
L2KT36

**Siemens Material Number (SMN):** 10381654  
10381657

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

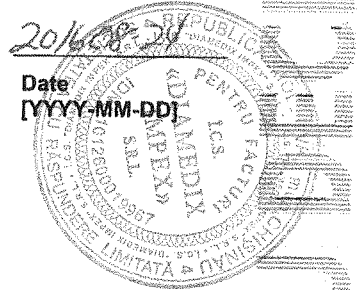
**Document Identifier:** EC DEC\_IMM 2000 Total T3 L2KT3

**Version:** 01

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**Signature:**

Anita Wample  
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.  
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

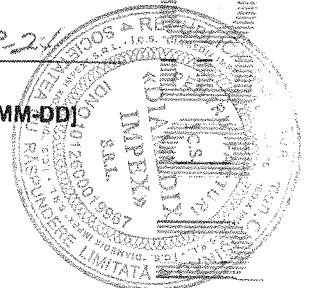
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**Signature:**

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

2016-08-24

Date  
[YYYY-MM-DD]



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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 Testosterone

**Catalogue Number (REF):** L2KTW2  
L2KTW6

**Siemens Material Number (SMN):** 10381190  
10381191

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

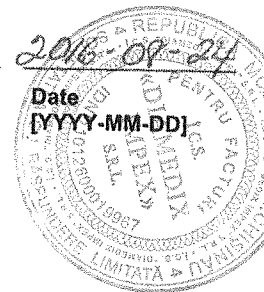
**Document Identifier:** EC DEC\_IMM 2000 Total Testosterone L2KTW

**Version:** 01

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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



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 Unconjugated Estriol (UE3)

**Catalogue Number (REF):** L2KUE32  
L2KUE36

**Siemens Material Number (SMN):** 10381192  
10381171

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

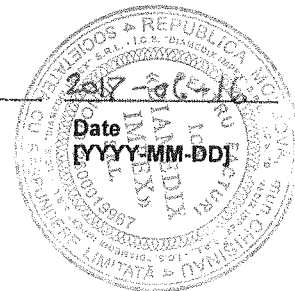
**Document Identifier:** EC DEC\_IMM 2000 Unconjugated Estriol L2KUE3

**Version:** 01

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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



## 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 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

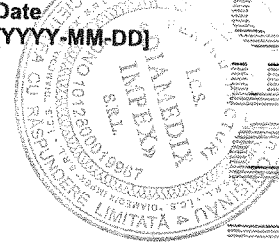
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**Signature:**

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

2016-08-24

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 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

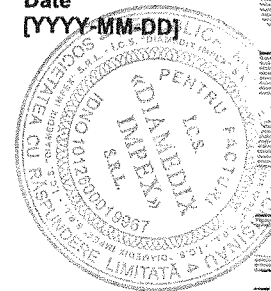
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**Signature:**

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

2016-08-24

Date  
[YYYY-MM-DD]



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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

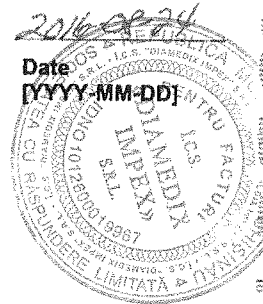
**Document Identifier:** EC DEC\_IMM 2000 Homocysteine L2KHO

**Version:** 01

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**Signature:**

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



Vertical text on the right side of the page, possibly a barcode or identification code.

# SIEMENS

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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 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

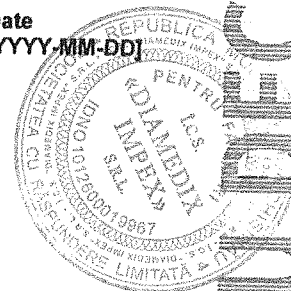
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
This declaration supersedes any declaration issued previously for the same product.*

**Signature:**

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

2017-07-05

Date  
[YYYY-MM-DD]



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

**Product Name:** IMMULITE 2000 Pylilinks-D

**Catalogue Number (REF):** L2KPD2

**Siemens Material Number (SMN):** 10381461

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Pylilinks-D L2KPD

**Version:** 01

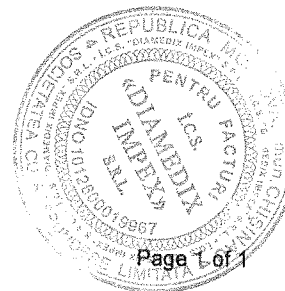
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
This declaration supersedes any declaration issued previously for the same product.*

**Signature:**

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

2016-08-24

Date  
[YYYY-MM-DD]



Vertical text on the right side of the page, likely a barcode or identification code, consisting of a series of vertical bars of varying heights.

## 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):** L2KVB2  
L2KVB6

**Siemens Material Number (SMN):** 10380914  
10380913

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Vitamin B12 L2KVB

**Version:** 01

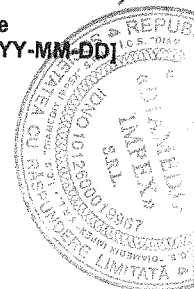
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
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**Signature:**

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

2016-08-24

Date  
[YYYY-MM-DD]



DECLARATION OF CONFORMITY

# 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

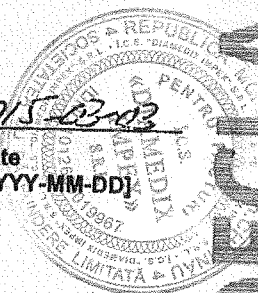
**Version:** 01

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

2015-03-03  
Date  
[YYYY-MM-DD]



EC 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 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

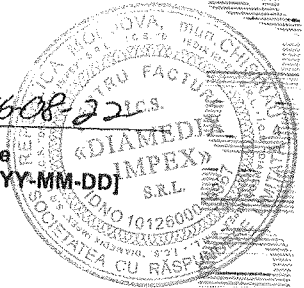
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**Signature:**

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

20160822

Date  
[YYYY-MM-DD]





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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

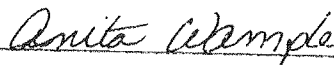
**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Folic Acid L2KFO

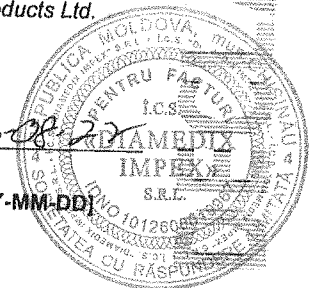
**Version:** 01

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**Signature:**

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

2016-08-27  
Date  
[YYYY-MM-DD]



## 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 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

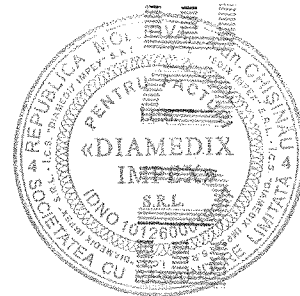
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
This declaration supersedes any declaration issued previously for the same product.*

**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



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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

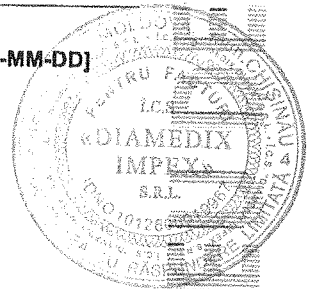
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
This declaration supersedes any declaration issued previously for the same product.*

**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



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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 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

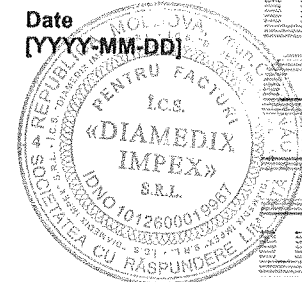
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
This declaration supersedes any declaration issued previously for the same product.*

**Signature:**

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

20160822

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 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

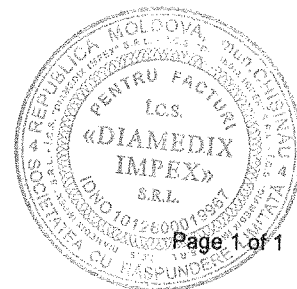
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
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**Signature:**

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

2016-08-19

Date  
[YYYY-MM-DD]



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## 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/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

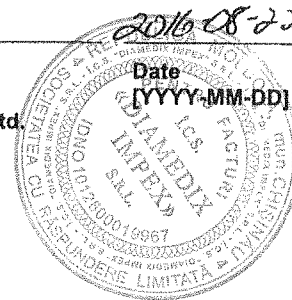
**Document Identifier:** EC DEC\_IMM 2000 Free PSA L2KPF

**Version:** 01

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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



*[Vertical text on the right margin, likely bleed-through from the reverse side of the page]*

## 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 Quantitative IgG

**Catalogue Number (REF):** L2KTXP2

**Siemens Material Number (SMN):** 10381323

**Classification:** ANNEX II, List B


**Conformity Assessment Route:** ANNEX IV

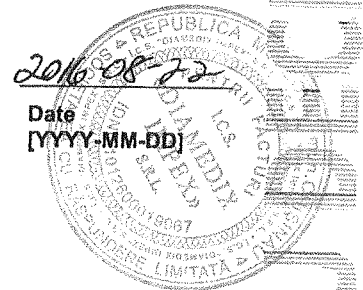
**Notified Body:** Lloyd's Register Quality Assurance Ltd.  
1 Trinity Park, Bickenhill Lane  
Solihull, B37 7ES, UK  
Identification No. 0088

**Document Identifier:** EC DEC\_IMM 2000 Toxoplasma Quantitative IgG L2KTXP

**Version:** 01

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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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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 ( $\mu$ -Capture)

**Catalogue Number (REF):** L2KTZ2

**Siemens Material Number (SMN):** 10381298

**Classification:** ANNEX II, List B

**Conformity Assessment Route:** ANNEX IV

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

**Document Identifier:** EC DEC\_IMM 2000 Toxoplasma IgM ( $\mu$ -Capture) L2KTZ

**Version:** 01

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**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



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

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

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

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

**Product Name:** IMMULITE 2000 Prolactin

**Catalogue Number (REF):** L2KPR2  
L2KPR6

**Siemens Material Number (SMN):** 10381200  
10381199

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Prolactin L2KPR

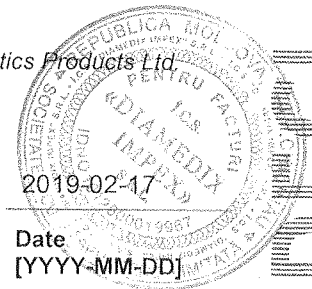
**Version:** 02

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

**Signature:** Robak  
Malgorzata

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

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 23:41:42 Z



Date  
[YYYY-MM-DD]

## 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 Intact PTH Control Module

**Catalogue Number (REF):** LPHCM

**Siemens Material Number (SMN):** 10385354

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM PTH Control Module LPHCM

**Version:** 01

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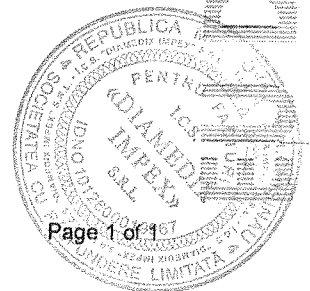
**Signature:**

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

2016-08-24

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

Vertical text on the right side of the page, likely a barcode or reference information.



## 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

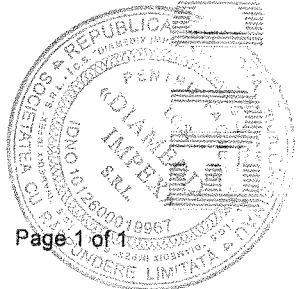
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**Signature:**

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

2016-08-24

Date  
[YYYY-MM-DD]



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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 IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 FSH L2KFS

**Version:** 01

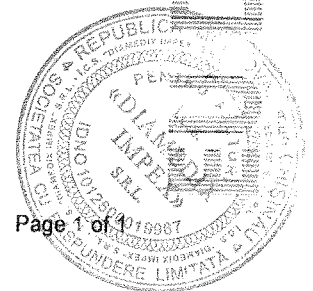
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**Signature:**

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

2016-08-24

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



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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 GI-MA

**Catalogue Number (REF):** L2KGI2

**Siemens Material Number (SMN):** 10380988

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 GI-MA L2KGI

**Version:** 01

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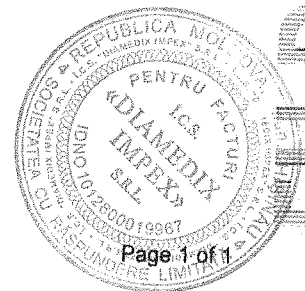
**Signature:**

*Anita Wample*

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

2016-08-24

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 H. pylori IgG

**Catalogue Number (REF):** L2KHPG2  
L2KHPG6

**Siemens Material Number (SMN):** 10381336  
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**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 H. pylori IgG L2KHPG

**Version:** 01

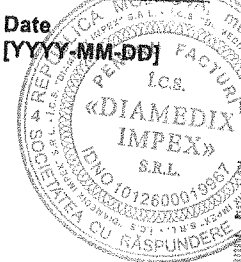
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
This declaration supersedes any declaration issued previously for the same product.*

**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



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  
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**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

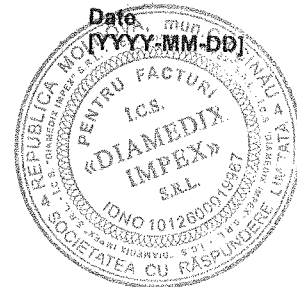
**Document Identifier:** EC DEC\_IMM 2000 Third Generation TSH L2KTS

**Version:** 01

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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 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

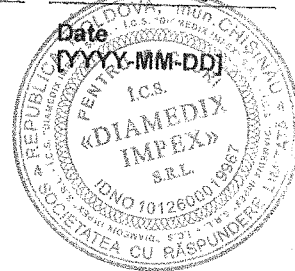
**Version:** 01

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**Signature:**

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

2016-08-22



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 AFP

**Catalogue Number (REF):** L2KAP2  
L2KAP6

**Siemens Material Number (SMN):** 10381187  
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**Classification:** General IVD

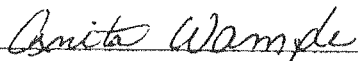
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**Document Identifier:** EC DEC\_IMM 2000 AFP L2KAP

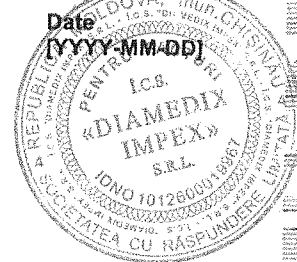
**Version:** 01

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2016-08-22



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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 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

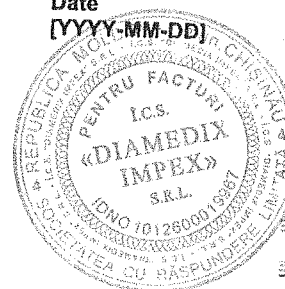
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Head of Quality Management  
Siemens Healthcare Diagnostics Products Ltd.  
Llanberis Gwynedd LL55 4EL, UK

2016-08-22

Date  
[YYYY-MM-DD]



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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 Allergy Specific IgG

**Catalogue Number (REF):** L2KGG2  
L2KGG6

**Siemens Material Number (SMN):** 10380877  
10380880

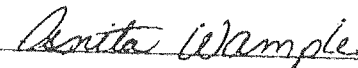
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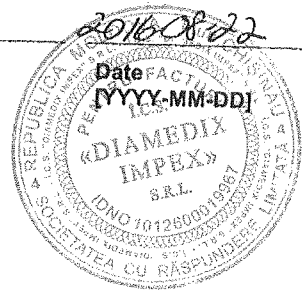
**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Allergy Specific IgG L2KGG

**Version:** 01

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



*[Vertical text on the right margin, likely bleed-through from the reverse side of the page]*

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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-TG Ab

**Catalogue Number (REF):** L2KTG2  
L2KTG6

**Siemens Material Number (SMN):** 10381659  
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**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Anti-TG Ab L2KTG

**Version:** 01

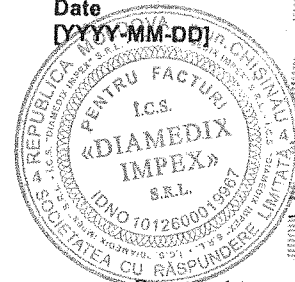
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Siemens Healthcare Diagnostics Products Ltd.  
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

Date  
[YYYY-MM-DD]



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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 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

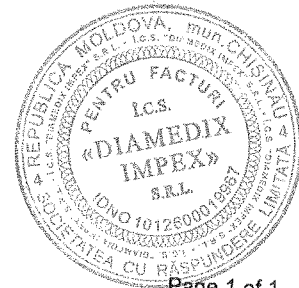
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**Signature:**

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

2016-08-22

Date  
[YYYY-MM-DD]



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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 Calcitonin

**Catalogue Number (REF):** L2KCL2

**Siemens Material Number (SMN):** 10381446

**Classification:** General IVD

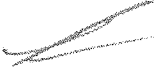
**Conformity Assessment Route:** ANNEX III

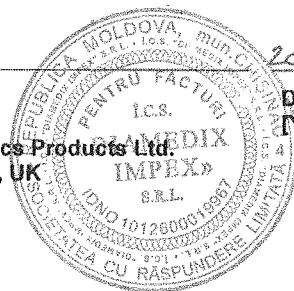
**Document Identifier:** EC DEC\_IMM 2000 Calcitonin L2KCL

**Version:** 01

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**Signature:**

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



2017-06-16  
Date  
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

# SIEMENS

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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 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

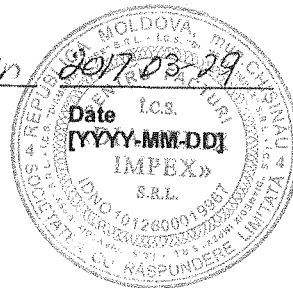
**Version:** 01

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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

# SIEMENS

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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

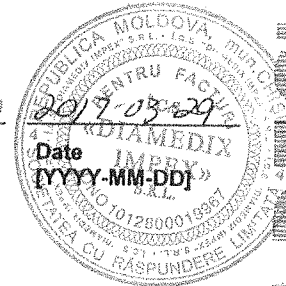
**Version:** 01

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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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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 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

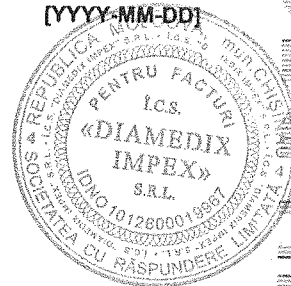
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**Signature:**

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

2016-08-24

Date  
[YYYY-MM-DD]



Vertical text on the right margin, likely a barcode or identification code, including the number 10381450.

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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 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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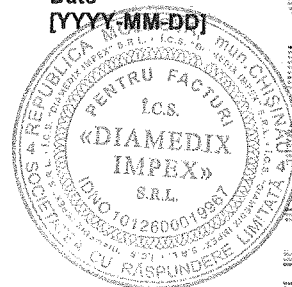
**Signature:**

*Anita Wample*

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

Date  
[YYYY-MM-DD]

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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

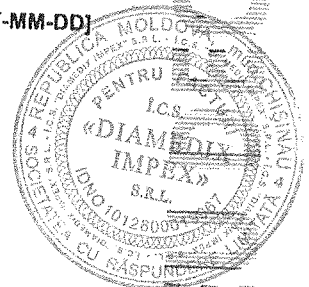
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Siemens Healthcare Diagnostics Products Ltd.  
Llanberis Gwynedd LL55 4EL, UK

2016-08-22

Date  
[YYYY-MM-DD]



DECLARATION OF CONFORMITY

# 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.

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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

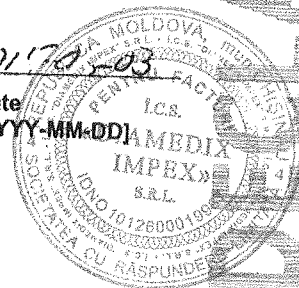
**Version:** 01

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Llanberis Gwynedd, LL55 4EL, UK

Date  
[YYYY-MM-DD]



DECLARATION OF CONFORMITY  
EC

# SIEMENS

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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 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

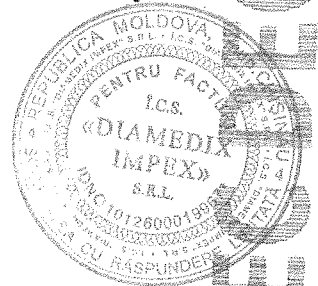
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Llanberis Gwynedd, LL55 4EL, UK

2015-03-03

Date  
[YYYY-MM-DD]



DECLARATION OF CONFORMITY

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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 Estradiol

**Catalogue Number (REF):** L2KE22  
L2KE26

**Siemens Material Number (SMN):** 10381178  
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**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Estradiol L2KE2

**Version:** 01

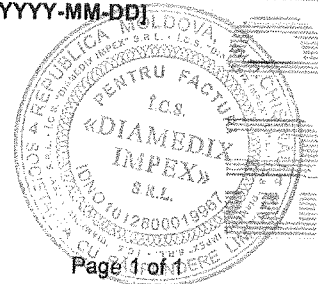
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2016-08-22

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[YYYY-MM-DD]



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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 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

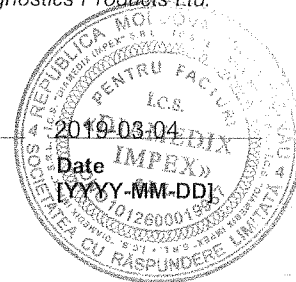
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**Signature:** Robak  
Malgorzata

Digitally signed by Robak Malgorzata  
DN: serialNumber=20020808,  
givenName=Malgorzata, sn=Robak, o=Siemens,  
c=Robak Malgorzata  
Reason: I am approving this document  
Date: 2019.03.04 10:09:38 Z

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

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



EU DECLARATION OF CONFORMITY

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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 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

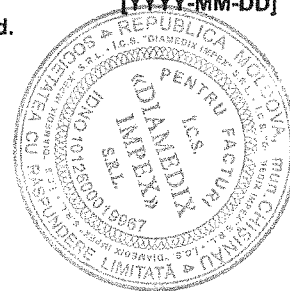
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Head of Quality Management  
Siemens Healthcare Diagnostics Products Ltd.  
LLanberis Gwynedd LL55 4EL, UK

2016 08 24

Date  
[YYYY-MM-DD]





# SIEMENS

## EU Declaration of Conformity



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

**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc.  
62 Flanders-Bartley Road  
Flanders, NJ, 07836, USA

**Place of Manufacture:** CARCLO TECHNICAL PLASTICS  
Grant Road  
Tucson, AZ 85705, USA  
  
Hoover Precision Products  
1390 Industrial Park Dr.,  
Sault Ste. Marie, MI 49783, USA

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

**Product Name:** IMMULITE 2000 Systems Reaction Tubes

**Catalogue Number (REF):** LRXT

**Siemens Material Number (SMN):** 10385206

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** DoC\_IMMULITE 2000\_RxnTubes

**Version:** 4.0

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

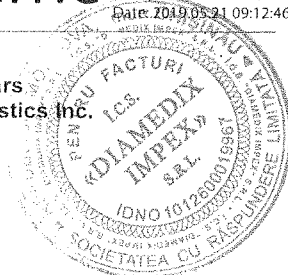
**Signature:**

**Ryan Sherrie**

Digitally signed by Ryan Sherrie  
DN: serialNumber=Z0026ZFR, givenName=Sherrie,  
sn=Ryan, o=Siemens, cn=Ryan Sherrie  
Date: 2019.05.21 09:12:46 -04'00'

Sherrie Ryan  
Sr Manager Regulatory Affairs  
Siemens Healthcare Diagnostics Inc.  
Newark, DE 19714

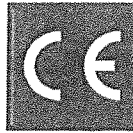
**Date**  
[YYYY-MM-DD]



EU DECLARATION OF CONFORMITY

## 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):

Product name (English):

IMMULITE 2000 / IMMULITE 2500 Waschmodul

IMMULITE 2000 / IMMULITE 2500 Probe Wash Module

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

L2PWSM

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

L2PWSM

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Address (international):

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

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

Bestätigung / Authorization:

Director Quality/Regulatory

Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2011-04-14

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



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

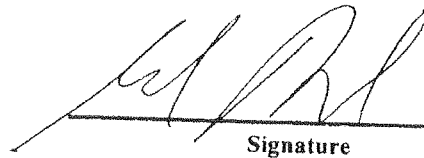
Device name: IMMULITE® 2000 Chemiluminescent Substrate

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

Dir. of QA - Los Angeles

Title

