

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 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: 02

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

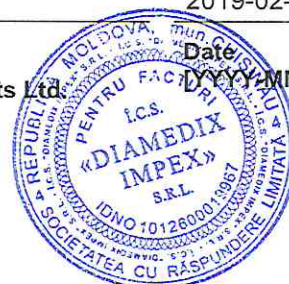
Signature:

**Robak
Malgorzata**

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

2019-02-17

Malgorzata Robak
Regulatory Affairs Supervisor
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.
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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-TPO Ab

Catalogue Number (REF): L2KTO2
L2KTO6

Siemens Material Number (SMN): 10381650
10381649

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Anti-TPO Ab L2KTO

Version: 02

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

Signature:

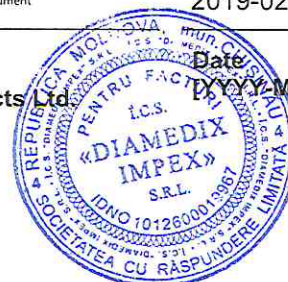
**Robak
Malgorzata**

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

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF,
givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.04 14:37:08 Z

2019-02-04

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 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



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.*

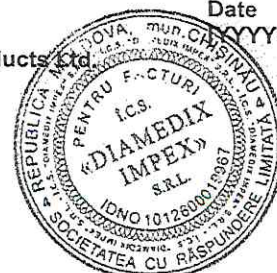
Signature: Robak
Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=ZC020NKF,
givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.09.25 09:58:23 +01'00'

2019-09-25

Malgorzata Robak
Regulatory Affairs Supervisor
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

Product Name: IMMULITE 2000 CEA

Catalogue Number (REF): L2KCE2
L2KCE6

Siemens Material Number (SMN): 10380994
10380995

Classification: General IVD

Conformity Assessment Route: ANNEX III

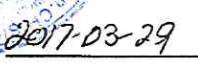
Document Identifier: EC DEC_IMM 2000 CEA L2KCE

Version: 01

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

Signature:


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


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 OM-MA

Catalogue Number (REF): L2KOP2

Siemens Material Number (SMN): 10380972

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 OM-MA L2KOP

Version: 01

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

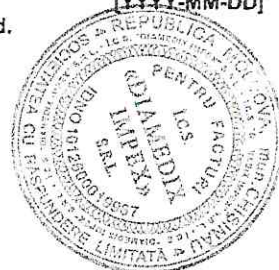
Signature:

Anita Wample

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

2016 08 24

Date
[YYYY-MM-DD]



EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



0088

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

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

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

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

Product Name: IMMULITE 2000 HBsAg

Catalogue Number (REF): L2KHB2

Siemens Material Number (SMN): 10381306

Classification: ANNEX II, List A

Conformity Assessment Route: ANNEX IV

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

Document Identifier: EC DEC_IMM 2000 HBsAg L2KHB

Version: 02

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

Signature:

Robak
Malgorzata

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

Digitally signed by Robak Malgorzata
DN: serialNumber=2002684F,
givenName=Malgorzata, sn=Robak, o=Siemens,
cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.03.04 10:05:38 Z



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

20/6/2018-24

Date
[YYYY-MM-DD]



DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity



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

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

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

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



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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

*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.*

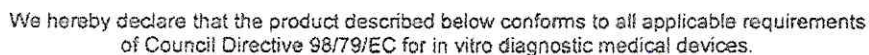
Signature:


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



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

EU DECLARATION OF CONFORMITY



2016-08-22

Date [YYYY-MM-DD]

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S.A.
190687
LIMITATA

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



EU DECLARATION OF CONFORMITY

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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 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

*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

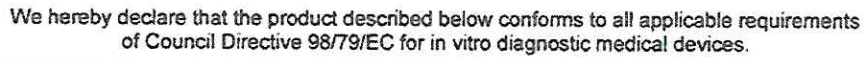
Date

2016-08-24
[YYMMDD]



EU DECLARATION OF CONFORMITY

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 Anti-HBc

Catalogue Number (REF): L2KHC2

Siemens Material Number (SMN): 10381311

Classification: ANNEX II, List A

Conformity Assessment Route: ANNEX IV

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

Document Identifier: EC DEC_IMMULITE® 2000 Anti-HBc

Version: 03

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

Signature: Robak
Malgorzata

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF,
givenName=Malgorzata, sn=Robak,
o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.09.26 22:50:36 +01'00'

Date
2019-09-26
[YYYY-MM-DD]

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



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 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:

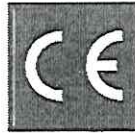

Kevin Owen
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK



EU DECLARATION OF CONFORMITY

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):

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]:



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 Reinigungsmodul

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]:

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

Dr

*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

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

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'

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

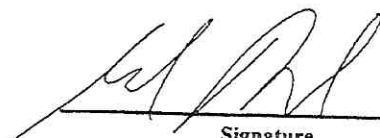
Device name: IMMULITE® 2000 Chemiluminescent Substrate

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:

 08/17/09
Signature Date

Name/Title of Signatory:

Kambiz Drake Dir. of QA - Los Angeles
Print Name Title





BIO-RAD LABORATORIES
CLINICAL DIAGNOSTICS GROUP
EC DECLARATION OF CONFORMITY

MANUFACTURER:

Bio-Rad Laboratories, QSD

ADDRESS:

Bio-Rad Laboratories, QSD
9500 Jeronimo Rd,
Irvine CA 92618

EUROPEAN AUTHORIZED
REPRESENTATIVE:

Bio-Rad
3, Boulevard Raymond Poincare
Marnes-la-Coquette, France 92430

PRODUCT(S) NAME(S) and CATALOG NUMBER(S):
Lyphochek® Immunoassay Plus Control

Catalog Number: 370, 371, 372, 373, 370X

CLASSIFICATION:

- ☐ ANNEX II-A
☒ ANNEX II-B

- ☐ DEVICE FOR SELF TESTING
☐ OTHER DEVICE

CONFORMITY ROUTE

- ☐ ANNEX III
☒ ANNEX IV.3 Full Quality System
☐ ANNEX IV.4 Product Design Examination

EC CERTIFICATE No.: 19347-1
Name of Notified Body : LNE/G-MED
Notified Body Identification No.: 0459
Expiration Date : 27.11.2013

- ☐ ANNEX V Type Examination

EC CERTIFICATE No.:
Name of Notified Body :
Notified Body Identification No.:
Expiration Date:

- ☐ ANNEX VII Production Quality System

NEW PRODUCT(S) (Notification according to article 10 point 4)

☐ YES

☒ NO

GENERIC DEVICE GROUP CODE:

EDMS Nomenclature: 12-50-01-30
GMDN Nomenclature: None

GENERIC DEVICE GROUP TERM (EDMS Nomenclature): Multi Constituents Immunochemistry Controls

We hereby declare that the above mentioned product(s) meet(s) the provisions of the following Directives

APPLICABLE DIRECTIVE:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* Diagnostic medical devices

APPLICABLE HARMONIZED STANDARDS:

EN 13841:2002
EN ISO 14971: 2007
EN ISO 15225:2000
EN 375:2001

EN 980: 2008
EN 13485:2003
EN 13612:2002
EN 13640:2002

Signature

IRVINE CA USA

Issued in

12/9/10

Date

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