

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 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

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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 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

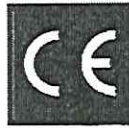
Kevin Owen
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
Llanberis Gwynedd LL55 4EL, UK



EU DECLARATION OF CONFORMITY

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]:



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

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:

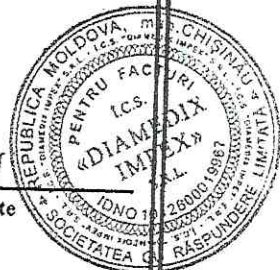

Signature

08/17/09
Date

Name/Title of Signatory:

Kambiz Drake
Print Name

Dir. of QA - Los Angeles
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 DEVICE FOR SELF TESTING
 ANNEX II-B 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 13641:2002
EN ISO 14971: 2007
EN ISO 15225:2000
EN 575:2001

EN 980:2006
EN 13485:2003
EN 13612:2002
EN 13840:2002

IRVINE CA USA

12/9/10

Signature

Issued in

Date

Vasif Vora

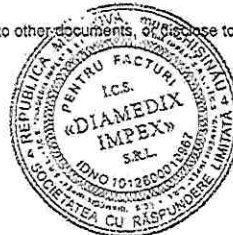
Regulatory Affairs Representative

Name

Function

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IBR-002-01, Rel 11, Effective Date 12-21-09



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