SIEMENS

EU Declaration of Conformity

CE

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:

2017-06-16

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIȘINĂU, I.C.S. PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Digitally signed by Marinescu Traian alin
Date: 2023.02.06 11:00:22 EET
Reason: MoldSign Signature
Location: Moldova

SIEMENS

EU Declaration of Conformity

CE

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 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

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

Signature: Anita Wampole for Kevin Owen

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

Date [YYYY-MM-DD] 2017-03-29

SIEMENS

Siemens Healthcare Diagnostics
Products GmbH

Konformitätserklärung

Declaration of Conformity

CE

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]:*

SIEMENS

EU Declaration of Conformity

CE

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 Affiars
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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

Manufacturer:

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

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If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.

Device type:	**In Vitro Diagnostic Medical Device**
Device name:	**IMMULITE® 2000 Chemiluminescent Substrate**
Catalog number:	**L2SUBM**
National and other standards and technical specifications:	**EN 375, EN 980, ISO 13485, EN 13612, EN 13640, EN 13641, ISO 14971, ISO/IEC 17050-1, 2, EN 17511, 21 CFR 820**
EU Representative:	**Siemens Healthcare Diagnostics Limited** **Faraday House** **Sir William Siemens Square, Frimley** **Camberley, GU16 8QD** **United Kingdom**

Signature/Date of Manufacturer or Responsible Party: _____ (Signature) 08/17/09 (Date)

Name/Title of Signatory: Kamhiz Drake (Print Name) Dir. QA-Los Angeles (Title)

BIO-RAD

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 13641:2002
EN ISO 14971: 2007
EN ISO 15225:2000
EN 375:2001
EN 980: 2008
EN 13485:2003
EN 13612:2002
EN 13640:2002

Signature	Issued in	Date
	IRVINE CA USA	12/9/10

Name	Function
Vasif Vora	Regulatory Affairs Representative