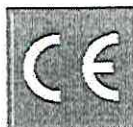


Konformitätserklärung

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):

12PWSM

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

12PW5M

IVD-Kategorie / IVD Category:

Sonstige

Others	
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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

7. AL

Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

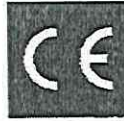
2011-04-14

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): IMMULITE 2000 / IMMULITE 2500 Reinigungsmodul	Product name (English): IMMULITE 2000 / IMMULITE 2500 Probe Cleaning Kit
--	--

Produkt-Nr. / Product No. (REF): L2KPM
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Packungsgröße(n) / Package Size(s) (REF): L2KPM

IVD-Kategorie / IVD Category: Sonstige	Others
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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
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Bestätigung / Authorization: Director Quality/Regulatory
Unterschrift / Signature
Dr. Jörg Amborn
Name / Name
2011-04-05
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

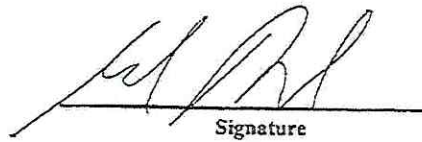
Device name: IMMULITE® 2000 Chemiluminescent Substrate

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:

 08/17/19
Signature Date

Name/Title of Signatory:

Kambiz Drake D.C. QA - Los Angeles
Print Name Title

