

EC Declaration of Conformity

Application of Directives:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices
 - 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
-

Means of conformity:

The following products are in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III,
- Directive 2011/65/EU by drawing up the required technical documentation and carrying out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC.

Product identification:

Product name: Automated Blood Coagulation Analyzer CS-2100i
Model name: CS-2100i
Classification: Other device (except Annex II and self-testing devices)

Authorised representative:

Name: SYSMEX EUROPE GMBH
Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Takeshi Kubota Date: 10. Aug. 2015
Takeshi Kubota, Managing Director

Legal Manufacturer:

Name: SYSMEX CORPORATION
Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

Authorised officer: Hiroshi Yamane Date: 31 July, 2015
Hiroshi Yamane, Executive Vice President

EC Declaration of Conformity

Application of Council Directive:

98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means of conformity:

The following product is in conformity with Directive **98/79/EC** based on the test results using harmonised standards in accordance with Article 5 of the Directive.

Product identification:

Product name: CA CAL S
Serial (Lot) No. From A2001

Manufacturer:

Name: SYSMEX CORPORATION
Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073
Country: Japan

Authorised representative:

Name: SYSMEX EUROPE GMBH
Address: Bornbarch 1, 22848 Norderstedt
Country: Germany

Authorised officer:


Iwane Matsui

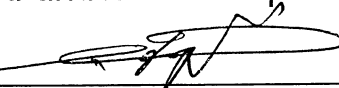
Position: President

Date: April 4th, 2002

Place: Norderstedt, Germany

This certificate was issued under sole responsibility of:

Authorised officer:


Tokuhiko Okada

Position: Vice President, Technology Control

Date: February 1st, 2002

Place: Japan

EC Declaration of Conformity

Application of Council Directive:

98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means of conformity:

The following product is in conformity with Directive 98/79/EC based on the test results using harmonised standards in accordance with Article 5 of the Directive.

Product identification:

Product name: CA CLEAN I

Manufacturer:

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073

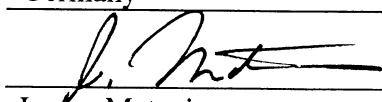
Country: Japan

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt

Country: Germany

Authorised officer: 

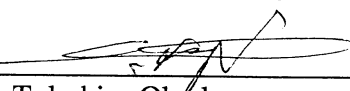
Iwane Matsui

Position: President

Date: 9TH JANUARY 2002

Place: NORDERSTEDT, GERMANY

This certificate was issued under sole responsibility of:

Authorised officer: 

Tokuhiko Okada

Position: Vice President, Technology Control

Date: November 7, 2001

Place: Japan

EC Declaration of Conformity

Application of Council Directive:

98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means of conformity:

The following product is in conformity with Directive 98/79/EC based on the test results using harmonised standards in accordance with Article 5 of the Directive.

Product identification:

Product name: CA CLEAN II

Manufacturer:

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073

Country: Japan

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt

Country: Germany

Authorised officer: 

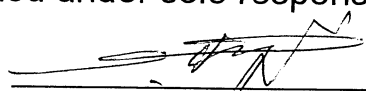
Iwane Matsui

Position: President

Date: 9TH JANUARY 2002

Place: NORDERSTEDT, GERMANY

This certificate was issued under sole responsibility of:

Authorised officer: 

Tokuhiko Okada

Position: Vice President, Technology Control

Date: November 7, 2001

Place: Japan

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):

Calciumchlorid-Lösung

Product name (English):

Calcium Chloride Solution

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

ORHO

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

ORHO 37

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]:

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):

Calciumchlorid-Lösung

Product name (English):

Calcium Chloride Solution

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

ORHO

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

ORHO 37

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

J. Amborn

Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2011-04-05

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

EC Declaration of Conformity

Application of Directives:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices
 - 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
-

Means of conformity:

The following products are in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III,
- Directive 2011/65/EU by drawing up the required technical documentation and carrying out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC.

Product identification:

Product name: Automated Blood Coagulation Analyzer CA-600 series
Model name: CA-620, CA-650, CA-660
Classification: Other device (except Annex II and self-testing devices)

Authorised representative:

Name: SYSMEX EUROPE GMBH
Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Takeshi Kubota Date: 10. Aug. 2015
Takeshi Kubota, Managing Director

Legal Manufacturer:

Name: SYSMEX CORPORATION
Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

Authorised officer: Hiroshi Yamane Date: 31 July, 2015
Hiroshi Yamane, Executive Vice President



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):

Kontroll-Plasma N

Product name (English):

Control Plasma N

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

ORKE

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

ORKE 41

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

2008-09-03

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



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):

Kontroll-Plasma P

Product name (English):

Control Plasma P

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

OUPZ

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

OUPZ 17

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

2008-09-03

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

EC Declaration of Conformity

Application of Council Directive:

98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means of conformity:

The following product is in conformity with Directive 98/79/EC based on the test results using harmonised standards in accordance with Article 5 of the Directive.

Product identification:

Product name: CUVETTE

Model: SUC-400A

Manufacturer:

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073

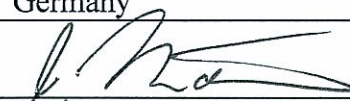
Country: Japan

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt

Country: Germany

Authorised officer: 

Iwane Matsui

Position: Executive Vice Chairman & CEO

Date: 4TH SEP. 2006

Place: Germany

This certificate was issued under sole responsibility of:

Authorised officer: 

Mitsuru Watanabe

Position: Vice President, R&D Strategic Planning

Date: 30th Aug. 2006

Place: Japan



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):

Dade CA System-Puffer

Product name (English):

Dade CA System Buffer

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

B4265-35

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

B4265-35

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

2008-09-03

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 Fehler! Verweisquelle konnte nicht gefunden werden..

Produktname (deutsch):

Dade Fibrinogen-Bestimmungsreagenzien

Product name (English):

Dade Fibrinogen Determination Reagents

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

B4233-15SY

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

B4233-15SY

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

G. Thedinga

Unterschrift / Signature

Dr. Gertrud Thedinga

Name /Name

2009-10-20

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 Fehler! Verweisquelle konnte nicht gefunden werden..

Produktname (deutsch):

Dade Fibrinogen-Bestimmungsreagenzien

Product name (English):

Dade Fibrinogen Determination Reagents

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

B4233-15SY

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

B4233-15SY

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

G. Thedinga

Unterschrift / Signature

Dr. Gertrud Thedinga

Name /Name

2009-10-20

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



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):

Dade Innovin

Product name (English):

Dade Innovin

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

B4212-40, -50, -100

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

B4212-40, -50, -100

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

2008-09-03

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



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):

Dade Innovin

Product name (English):

Dade Innovin

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

B4212-40, -50, -100

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

B4212-40, -50, -100

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

2008-09-03

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



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):

Dade Thrombin Reagenz

Product name (English):

Dade Thrombin Reagent

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

B4233-25, -27

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

B4233-25, -27

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

J. A. C.

Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2008-09-03

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



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):

Fibrinogen Kalibrator Kit

Product name (English):

Fibrinogen Calibrator Kit

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

OQVK

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

OQVK 11

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

2008-09-03

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



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):

INNOVANCE D-Dimer Controls

Product name (English):

INNOVANCE D-Dimer Controls

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

OPDY

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

OPDY 03

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

2008-09-03

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



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):

INNOVANCE D-Dimer

Product name (English):

INNOVANCE D-Dimer

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

OPBP

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

OPBP 03, OPBP 07

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

2008-09-03

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



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen.

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.

Hersteller:
Legal Manufacturer:

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

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

Produktname:
Product Name:

INNOVANCE Heparin Kalibrator
INNOVANCE Heparin Calibrator

Produkt-Nr (REF):
Catalogue Number (REF):

OPOB

Siemens Material Nummer (SMN):
Siemens Material Number (SMN):

10873453

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

OPOB 03

IVD Kategorie:
Classification:

Sonstige
General IVD

Konformitätsbewertungsverfahren:
Conformity Assessment Route:

ANHANG III
ANNEX III

Diese Konformitätserklärung ist unter alleiniger Verantwortung der Siemens Healthcare Diagnostics Products GmbH erstellt worden.

Diese Konformitätserklärung ersetzt jede vorher für dieses Produkt erstellte Konformitätserklärung.

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products GmbH.

This declaration supersedes any declaration issued previously for the same product.

Unterschrift:
Signature:

Name of Signatory: Dr. Gertrud Thedinga
Title of Signatory: Head of Regulatory Affairs
Siemens Healthcare Diagnostics Products GmbH
Marburg

2015-09-29

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

KONFORMITÄTSEKKLÄRUNG / EC DECLARATION OF CONFORMITY



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen.

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.

Hersteller:
Legal Manufacturer:

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

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

Produktname:
Product Name:

INNOVANCE Heparin
INNOVANCE Heparin

Produkt-Nr (REF):
Catalogue Number (REF):

OPOA

Siemens Material Nummer (SMN):
Siemens Material Number (SMN):

10873448

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

OPOA 03

IVD Kategorie:
Classification:

Sonstige
General IVD

Konformitätsbewertungsverfahren:
Conformity Assessment Route:

ANHANG III
ANNEX III

Diese Konformitätserklärung ist unter alleiniger Verantwortung der Siemens Healthcare Diagnostics Products GmbH erstellt worden.

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This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products GmbH.

This declaration supersedes any declaration issued previously for the same product.

Unterschrift:
Signature:

Name of Signatory: Dr. Gertrud Thedinga
Title of Signatory: Head of Regulatory Affairs
Siemens Healthcare Diagnostics Products GmbH
Marburg

2015-09-29

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



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen.

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.

Hersteller:

Legal Manufacturer:

Innerhalb Deutschland

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

International

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

Produktname:

Product Name:

INNOVANCE Heparin LMW Kontrolle 1

INNOVANCE Heparin LMW Control 1

Produkt-Nr (REF):

Catalogue Number (REF):

OPOE

Siemens Material Nummer (SMN):

Siemens Material Number (SMN):

10873449

Packungsgröße(n) (REF):

Package Size(s) (REF):

OPOE 03

IVD Kategorie:

Classification:

Sonstige

General IVD

Konformitätsbewertungsverfahren:

Conformity Assessment Route:

ANHANG III

ANNEX III

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This declaration supersedes any declaration issued previously for the same product.

Unterschrift:

Signature:

G. Thedinga

Name of Signatory: Dr. Gertrud Thedinga
Title of Signatory: Head of Regulatory Affairs
Siemens Healthcare Diagnostics Products GmbH
Marburg

2015-09-29

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



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen.

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.

Hersteller: Legal Manufacturer:	Innerhalb Deutschland Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	International Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg, Germany
Produktname: Product Name:	INNOVANCE Heparin LMW Kontrolle 2 INNOVANCE Heparin LMW Control 2	
Produkt-Nr (REF): Catalogue Number (REF):	OPOF	
Siemens Material Nummer (SMN): Siemens Material Number (SMN):	10873450	
Packungsgröße(n) (REF): Package Size(s) (REF):	OPOF 03	
IVD Kategorie: Classification:	Sonstige General IVD	
Konformitätsbewertungsverfahren: Conformity Assessment Route:	ANHANG III ANNEX III	

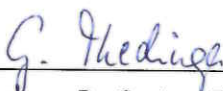
Diese Konformitätserklärung ist unter alleiniger Verantwortung der Siemens Healthcare Diagnostics Products GmbH erstellt worden.

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This declaration supersedes any declaration issued previously for the same product.

Unterschrift:
Signature:



Name of Signatory: Dr. Gertrud Thedinga
Title of Signatory: Head of Regulatory Affairs
Siemens Healthcare Diagnostics Products GmbH
Marburg

2015-09-29

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



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen.

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.

Hersteller:
Legal Manufacturer:

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

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

Produktname:
Product Name:

INNOVANCE Heparin UF Kontrolle 1
INNOVANCE Heparin UF Control 1

Produkt-Nr (REF):
Catalogue Number (REF):

OPOC

Siemens Material Nummer (SMN):
Siemens Material Number (SMN):

10873452

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

OPOC 03

IVD Kategorie:
Classification:

Sonstige
General IVD

Konformitätsbewertungsverfahren:
Conformity Assessment Route:

ANHANG III
ANNEX III

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Unterschrift:
Signature:

G. Thedinga

Name of Signatory: Dr. Gertrud Thedinga
Title of Signatory: Head of Regulatory Affairs
Siemens Healthcare Diagnostics Products GmbH
Marburg

2015-09-29

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

KONFORMITÄTserklärung / EC DECLARATION OF CONFORMITY



Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen.

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.

Hersteller: Legal Manufacturer:	Innerhalb Deutschland Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	International Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg, Germany
Produktname: Product Name:	INNOVANCE Heparin UF Kontrolle 2 INNOVANCE Heparin UF Control 2	
Produkt-Nr (REF): Catalogue Number (REF):	OPOD	
Siemens Material Nummer (SMN): Siemens Material Number (SMN):	10873451	
Packungsgröße(n) (REF): Package Size(s) (REF):	OPOD 03	
IVD Kategorie: Classification:	Sonstige General IVD	
Konformitätsbewertungsverfahren: Conformity Assessment Route:	ANHANG III ANNEX III	

Diese Konformitätserklärung ist unter alleiniger Verantwortung der Siemens Healthcare Diagnostics Products GmbH erstellt worden.

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This declaration supersedes any declaration issued previously for the same product.

Unterschrift:
Signature:

Name of Signatory: Dr. Gertrud Thedinga
Title of Signatory: Head of Regulatory Affairs
Siemens Healthcare Diagnostics Products GmbH
Marburg

2015-09-29

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

KONFORMITÄTSEKLAERUNG / EC 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):

Multifibren U

Product name (English):

Multifibren U

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

OWZG

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

OWZG 15, OWZG 19, OWZG 21, OWZG 23

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]:



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):

Pathromtin SL

Product name (English):

Pathromtin SL

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

OQGS

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

OQGS 29, OQGS 35

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

2008-09-03

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



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):

PT-Multi Calibrator

Product name (English):

PT-Multi Calibrator

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

OPAT

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

OPAT 03

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
2008-09-03
Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:

EC Declaration of Conformity

Application of Council Directive:

98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means of conformity:

The following product is in conformity with Directive 98/79/EC based on the test results using harmonised standards in accordance with Article 5 of the Directive.

Product identification:

Product: REACTION TUBE

Model: SU-40

Manufacturer:

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073

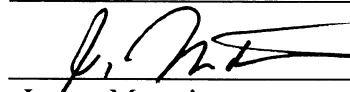
Country: Japan

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt

Country: Germany

Authorised officer: 

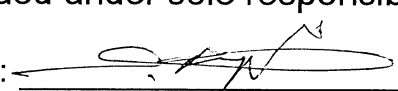
Iwane Matsui

Position: President

Date: 10TH JANUARY 2002

Place: NORDERSTEDT, GERMANY

This certificate was issued under sole responsibility of:

Authorised officer: 

Tokuhiro Okada

Position: Vice President, Technology Control

Date: November 16, 2001

Place: Japan

EC Declaration of Conformity

Application of Council Directive:

98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means of conformity:

The following product is in conformity with Directive 98/79/EC based on the test results using harmonised standards in accordance with Article 5 of the Directive.

Product identification:

Product: REACTION TUBE

Model: SUA-400A

Manufacturer:

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073

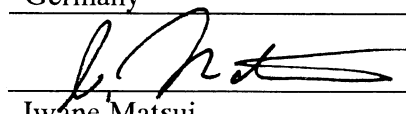
Country: Japan

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt

Country: Germany

Authorised officer: 

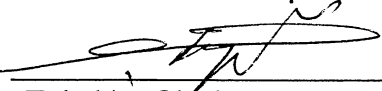
Iwane Matsui

Position: President

Date: 15TH MAY 2002

Place: Germany

This certificate was issued under sole responsibility of:

Authorised officer: 

Tokuhiko Okada

Position: Vice President, Technology Control

Date: March 15, 2002

Place: Japan

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):

Standard-Human-Plasma

Product name (English):

Standard Human Plasma

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

ORKL

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

ORKL 13, ORKL 17, ORKL 21

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]:

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):

Waschlösung für Gerinnungsanalyser

Product name (English):

Washing Solution for Coagulation Analyzers

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

OWZC

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

OWZC 39

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]: