

SIEMENS

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):

Thromborel S

Product name (English):

Thromborel S

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

OUHP

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

OUHP 29, OUHP 49

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

7. KS

Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2008-09-03

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



Sysmex

SYSMEX CORPORATION

Kodok
1-5-1 Wakunagomachi-Kuigandori, Chuo-ku, Kobe 651-0073, Japan
Phone : 81-78-265-0500
Fax : 81-78-265-0524

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 Wakunagomachi-Kuigandori, 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:

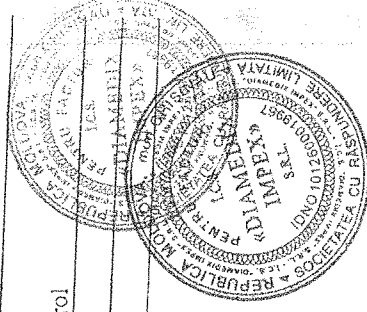
Authorised officer:

Tokuhiro Okada

Position: Vice President, Technology Control

Date: November 7, 2001

Place: Japan



Sysmex

SYSMEX CORPORATION

1-5-1 Wakoinohama, Nakagyo-ku, Kyoto 605-0073, Japan
Tel: 81-75-285-5350
Fax: 81-75-285-5354

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 Wakoinohama-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:

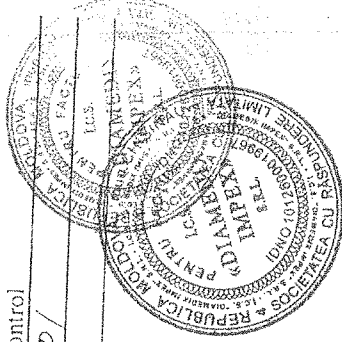
Authorised officer:


Tokuhiko Okada

Position: Vice President, Technology Control

Date: November 7, 2001

Place: Japan



SIEMENS

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):

Dade Actin FS Reagenz zur Bestimmung der APTT

Product name (English):

Dade Actin FS Activated PTT Reagent

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

B4218-20, -100

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

B4218-20, -100

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (Innereib 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

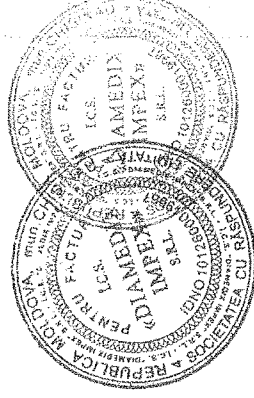
Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



Konformitätserklärung / Declaration of Conformity (DoC)

Seite / Page: 1 von / of 1

SIEMENS

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):
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-L

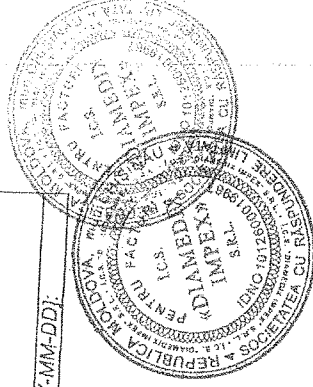
Unterschrift / Signature

Dr. Jörg Ansbom

Name / Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



SIEMENS

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 II 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 Owren's Veronal-Puffer

Product name (English):

Dade Owren's Veronal Buffer

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

B4234-25

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

B4234-25

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

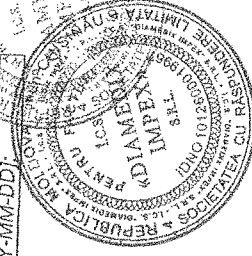
Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2008-09-03

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



Konformitätserklärung / Declaration of Conformity (DoC)

Seite / Page: 1 von / of 1

SIEMENS

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):
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

7. AS

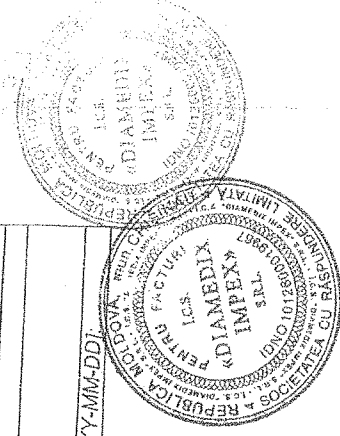
Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2008-09-03

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



SIEMENS

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 conform 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):
Test-Thrombin-Reagenz

Product name (English):
Test Thrombin Reagent

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

OWHM

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

OWHM 13

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

7. AS

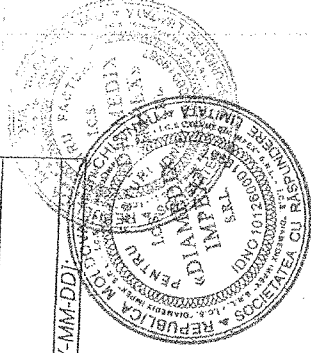
Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



SIEMENS

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Declaration of Conformity



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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

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

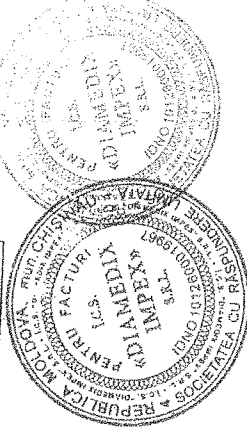
Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



SIEMENS

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):

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

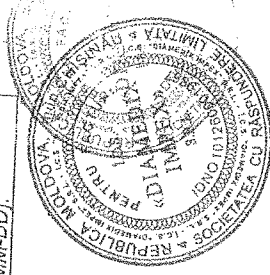
Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2008-09-03

Datum (JJJ-MM-TT) / Date (YYYY-MM-DD):



Konformitätserklärung



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 with In vitro Diagnostic assessment procedures as shown by conformity assessment procedures of Annex III.

ADVANCE D-Dimer Controls

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

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

IVD-Kategorie / IVD Category:

Hersteller / Manufacturer:

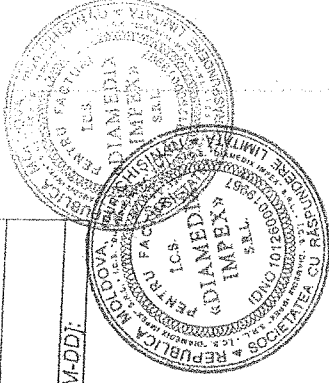
Adresse (Innerhalb Deutschland):

Healthcare Diagnostics Products GmbH
 Email-von-Behring-Str. 76
 35041 Marburg
 Germany

Director Quality/Regulatory

Name/Name

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



SIEMENS

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):

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

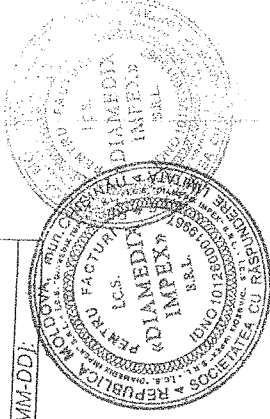
Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



Konformitätserklärung / Declaration of Conformity (DoC)

Seite / Page: 1 von / of 1

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 Deutschlands):

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

W. Schuy

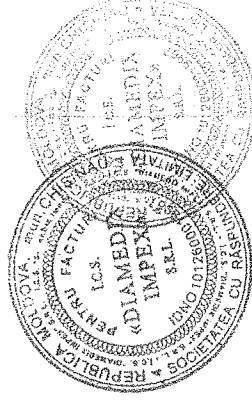
Unterschrift / Signature

Dr. Wilhelm Schuy

Name / Name

2009-08-05

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



sysmex

SYSMEX CORPORATION

Mak. to : I.E.S. Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Phone : 81-78-265-0000
Fax : 81-78-265-0024

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 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: 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

