

EC Declaration of Conformity

Application of Directives:

- 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 conformity assessment procedures in accordance with Annex III of the Directive.

Product identification:

Product name: CA CLEAN I

Classification: Other device (except Annex II and self-testing devices)

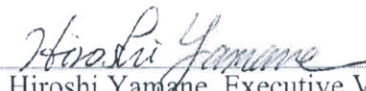
List of Applied Standards:

- Harmonised Standards used for conformity assessment are listed in the technical documentation.

Legal Manufacturer:

Name: SYSMEX CORPORATION

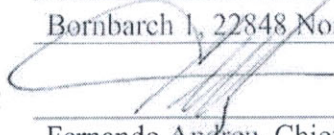
Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

Authorised officer:  Date: 13 March 2018
Hiroshi Yamane, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:  Date: MARCH 21ST 2018
Fernando Andreu, Chief Operations Officer

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until 25.05.2022 or until a revised declaration is Issued due to product modifications.

EC Declaration of Conformity

Application of Directives:

- 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 conformity assessment procedures in accordance with Annex III of the Directive.

Product identification:

Product name: CA CLEAN II

Classification: Other device (except Annex II and self-testing devices)

List of Applied Standards:

- Harmonised Standards used for conformity assessment are listed in the technical documentation.

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:

Hiroshi Yamane Date: 13 March 2018
Hiroshi Yamane, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Fernando Andreu Date: March 21st 2018
Fernando Andreu, Chief Operations Officer

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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 products are in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III,

Product identification:

Product name: CUVETTE

Model name: SUC-400A

Classification: Other device (except Annex II and self-testing devices)

List of Applied Standards:

- Harmonised Standards used for conformity assessment are listed in the technical documentation.

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:

Hiroshi Yamane

Date: 13 March 2018

Hiroshi Yamane, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Fernando Andreu

Date: 14 March 2018

Fernando Andreu, Chief Operations Officer

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until 25.05.2022 or until a revised declaration is issued due to product modifications.

Sysmex Corporation

1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

Tel. +81-78-265-0500 Fax. +81-78-265-0524

[Signature]
www.sysmex.co.jp



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 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]:



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 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):

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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):

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35041 Marburg
Germany

Bestätigung / Authorization:

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Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2008-09-03

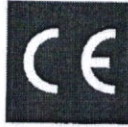
Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:



SIEMENS

Konformitätserklärung

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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):

Gerinnungsfaktor IX-Mangelplasma

Product name (English):

Coagulation Factor IX Deficient Plasma

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

OTXX

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

OTXX 17

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

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35041 Marburg

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2008-09-03

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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):

Dade Ci-Trol 1

Product name (English):

Dade Ci-Trol 1

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

291070

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

291070

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):

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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]:



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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):

Dade Ci-Trol 2

Product name (English):

Dade Ci-Trol 2

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

291071

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

291071

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]:

