

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

Hersteller / Manufacturer:

Others

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

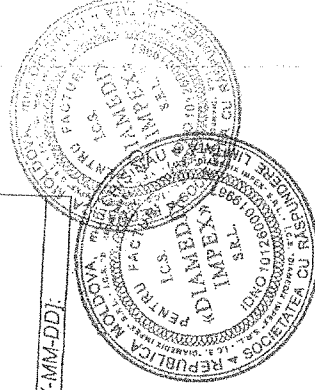
Unterschrift / Signature

Dr. Jörg Anborn

Name /Name

2008-09-03

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



SIEMENS

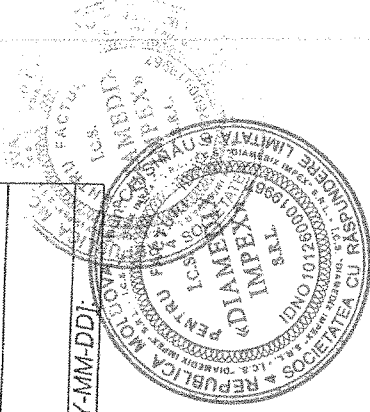
Konformitätserklärung

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):			
Packungsgröße(n) / Package Size(s) (REF):		B4234-25	
IVD-Kategorie / IVD Category:		B4234-25	
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):	Product name (English):
Dade Actin FS Reagenz zur Bestimmung der APTT	Dade Actin FS Activated PTT Reagent

Produkt-Nr. / Product No. (REF):
B4218-20, -100

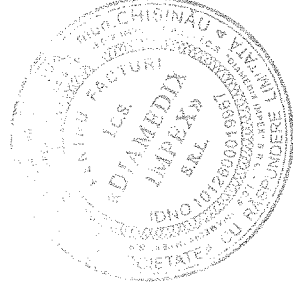
Packungsgröße(n) / Package Size(s) (REF):
B4218-20, -100

IVD-Kategorie / IVD Category:	Others
Sonstige	

Hersteller / Manufacturer:
Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschlands):	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
2008-09-03
Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:



Systemex

SYSTEMEX CORPORATION

Mail to : 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0872, Japan
Phone : 011-76-263-0500
Facsimile : 011-76-263-0524

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: SYSTEMEX CORPORATION

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

Country: Japan

Authorised representative:

Name: SYSTEMEX 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:

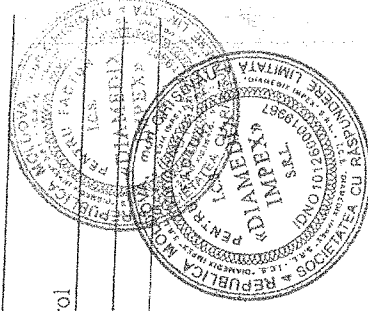
Authorised officer:

Tokuhiro Okada

Position: Vice President, Technology Control

Date: November 7, 2001

Place: Japan



Sysmex

SYSMEX CORPORATION

Mkt. to : 1-5-1 Wakinohama-Kaigandori Chuo-ku, Kobe 651-8573, 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: 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: Bombarch 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:

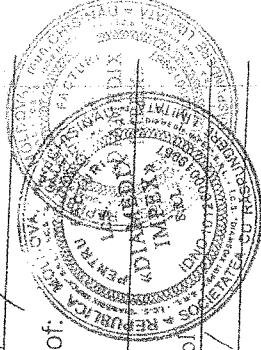
Vice President, Technology Control

Date:

November 16, 2001

Place:

Japan



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

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

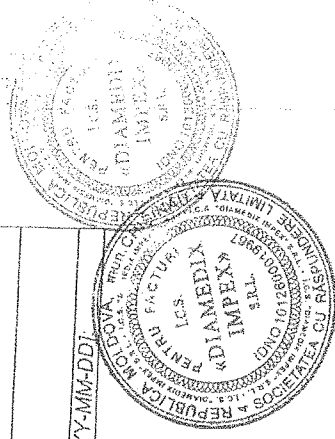
Unterschrift / Signature

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