SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):	*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]:*

REPUBLICA MOLDOVA «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019987 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Sysmex SYSMEX CORPORATION

Mail to : 1-5-1 Wakinohama-Kaigandori,Chuo-ku Kobe 651-0073,Japan
Phone : 81-78-265-0500
Facsimile : 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 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: Tokuhiro Okada
Position: Vice President, Technology Control
Date: November 7, 2001
Place: Japan

REPUBLICA MOLDOVA «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Sysmex SYSMEX CORPORATION

Mail to : 1-5-1 Wakinohama-Kaigandori,Chuo-ku,Kobe 651-0073,Japan
Phone : 81-78-265-0500
Facsimile : 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 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: [signature]
Iwane Matsui
Position: President
Date: 9TH JANUARY 2002
Place: NORDERSTEDT, GERMANY

This certificate was issued under sole responsibility of:

Authorised officer: [signature]
Tokuhiro Okada
Position: Vice President, Technology Control
Date: November 7, 2001
Place: Japan

REPUBLICA MOLDOVA, mun. Chişinău, PENTRU FACTURA I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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:*

Sonstige	*Others*

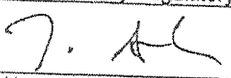
Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	*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



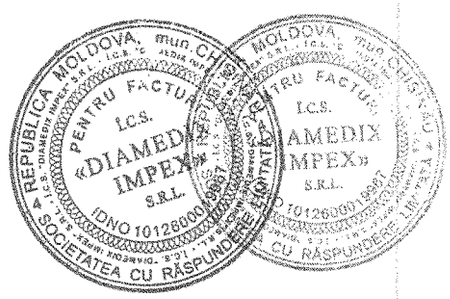
Unterschrift / *Signature*

Dr. Jörg Amborn

Name /*Name*

2008-09-03

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



SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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*

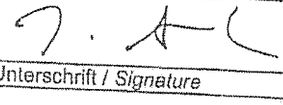
Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	***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



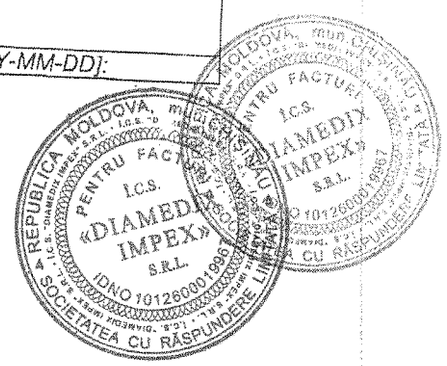
Unterschrift / *Signature*

Dr. Jörg Amborn

Name /*Name*

2008-09-03

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



SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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 Owren's Veronal-Puffer	*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):	*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]:*

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):***
INNOVANCE D-Dimer	*INNOVANCE D-Dimer*

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

OPBP

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

OPBP 03, OPBP 07

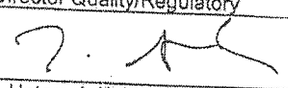
IVD-Kategorie / *IVD Category*:	
Sonstige	*Others*

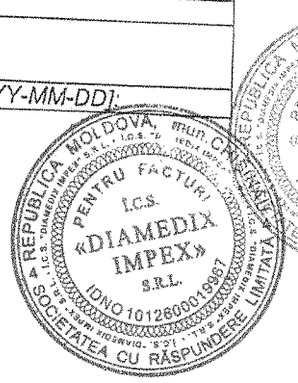
Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	*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]:*



SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):*
Test-Thrombin-Reagenz	*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):	*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]:*

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):	***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]:*

REPUBLICA MOLDOVA, mun. CHISINAU, I.C.S. «DIAMEDIX IMPEX» S.R.L. PENTRU FACTURI, IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):	*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]:*

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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 Ci-Trol 2	*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):	*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 Ambom

Name /*Name*

2008-09-03

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

REPUBLICA MOLDOVA, mun. CHIȘINĂU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019..., SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Digitally signed by Marinescu Traian Alin
Date: 2019.11.04 08:57:48 EET
Reason: MoldSign Signature
Location: Moldova

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):***
INNOVANCE D-Dimer Controls	*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:*

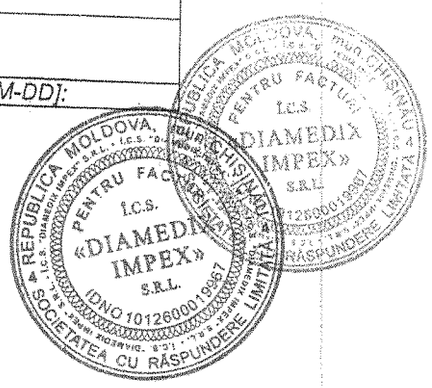
Siemens Healthcare Diagnostics Products GmbH

Adresse (Innerhalb Deutschland):	***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]:*



SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):*
PT-Multi Calibrator	*PT-Multi Calibrator*

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

OPAT

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

OPAT 03

IVD-Kategorie / *IVD Category*:

Sonstige	*Others*

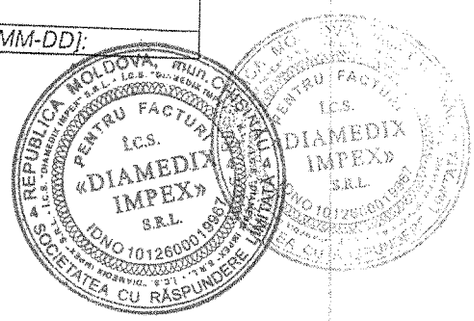
Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	*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]:*



SIEMENS

Siemens Healthcare Diagnostics
Products GmbH

Konformitätserklärung — *Declaration of Conformity*

CE

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
W. Schuy
Unterschrift / *Signature*
Dr. Wilhelm Schuy
Name /*Name*
2009-08-05
Datum [JJJJ-MM-TT] / *Date [YYYY-MM-DD]:*

REPUBLICA MOLDOVA, mun. CHIŞINĂU, PENTRU FACTURĂ, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019961, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Sysmex
SYSMEX CORPORATION
Mail to : 1-5-1 Wakinohama-Kaigandori Chuo-ku Kobe 651-0073 Japan
Phone : 81-78-265-0500
Facsimile : 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: Bornbarch 1, 22848 Norderstedt
Country: Germany
Authorised officer: [signature]
Iwane Matsui
Position: President
Date: 10TH JANUARY 2002
Place: NORDERSTEDT, GERMANY

This certificate was issued under sole responsibility of:

Authorised officer: [signature]
Tokuhiro Okada
Position: Vice President, Technology Control
Date: November 16, 2001
Place: Japan