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):*
Thromborel S	*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 Ambom
Name /*Name*
2008-09-03
Datum [JJJJ-MM-TT] / *Date [YYYY-MM-DD]:*

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: 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

CE

SIEMENS Healthineers

EU Declaration of Conformity

for Pathromtin SL

Siemens Healthcare Diagnostics Products GmbH hereby declares conformity to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU for the following In Vitro Diagnostic Device:

Product Name

Pathromtin SL

Intended Purpose Statement of Device

Pathromtin SL is an in vitro diagnostic reagent for the quantitative determination of activated partial thromboplastin time (APTT) as an aid to diagnosis, screening for hemostasis disorders and monitoring of unfractionated heparin in human sodium citrated plasma by means of automated, semi-automated and/or manual coagulometric methods. For APTT testing no international reference preparation or method is available.

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
OQGS29	10446066	10 x 5 mL
OQGS35	10446067	20 x 5 mL
10484200	10484200	20 x 5 mL (RiLiBÄK)

Basic UDI-DI (Basic Unique Device Identification)

0405686900191V5

Risk classification according to the rules of Annex VIII REGULATION (EU) 2017/746

Class C

Manufacturer and address of registered place of business

Manufacturer	Siemens Healthcare Diagnostics Products GmbH
Single Registration Number	DE-MF-000005039
Address	Emil-von-Behring-Str. 76 35041 Marburg Germany

Notified Body

Name	TÜV Rheinland LGA Products GmbH
Identification Number	0197
Address	Tillystr. 2 90431 Nürnberg Germany
Conformity Assessment Procedure	Annex IX

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):	*Product name (English):*
Calciumchlorid-Lösung	*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):	*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*
2009-11-05
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 Thrombin Reagenz	*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
7. A-L
Unterschrift / *Signature*
Dr. Jörg Amborn
Name /*Name*
2008-09-03
Datum [JJJJ-MM-TT] / *Date [YYYY-MM-DD]:*

REPUBLICA MOLDOVA, SOCIETATEA CU RĂSPUNDERE LIMITATĂ PENTRU FACTURA I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600015998

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):*
B4234-26

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]:*

Sysmex SYSMEX CORPORATION
Address : 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 «DIAMED-IMPEX» S.R.L. IDNO 1012600019957 SOCIETATEA CU RASPUNDERE LIMITATA

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 Thrombin Reagenz	*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
7. A C
Unterschrift / *Signature*
Dr. Jörg Amborn
Name /*Name*
2008-09-03
Datum [JJJJ-MM-TT] / *Date [YYYY-MM-DD]:*

CE

SIEMENS Healthineers

EU Declaration of Conformity

for INNOVANCE Antithrombin

Notified Body Certificate Number
HX 1512506-1

Common Specifications the product conforms with

Identifier	Title of Document
N/A	N/A

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products GmbH according to REGULATION (EU) 2017/746 for the following In Vitro Diagnostic Device and any other Union legislation as stated in the Conformity with Standards and supersedes any declaration issued previously for the same product.

Signature: A. Wiegand

Electronically signed by:
Andreas Wiegand
Reason: I am approving this document
Date: Aug 3, 2021 08:36 GMT+2

Email: ANDREAS.WIEGAND@SIEMENS-HEALTHINEERS.COM

Andreas Wiegand
Senior Director Regulatory Affairs
Siemens Healthcare Diagnostics Product GmbH
Marburg, Germany

Date:
2021-08-03

REPUBLICA MOLDOVA mun. CHIȘINĂU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012800019961 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

CE

SIEMENS Healthineers

EU Declaration of Conformity

for Coagulation Factor X Deficient Plasma

Siemens Healthcare Diagnostics Products GmbH hereby declares conformity to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU for the following In Vitro Diagnostic Device:

Product Name

Coagulation Factor X Deficient Plasma

Intended Purpose Statement of Device

Coagulation Factor X Deficient Plasma is an in vitro diagnostic reagent for use in assays for the quantitative, WHO- standardized determination of coagulation factor X (FX) activity as aid to diagnosis of congenital or acquired FX deficiencies in patients with bleeding disorders or at risk for FX deficiency in human sodium citrated plasma by means of automated, semi-automated and/or manual coagulometric methods.

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
OTXY13	10446415	3 x 1 mL

Basic UDI-DI (Basic Unique Device Identification)

0405686900861VX

Risk classification according to the rules of Annex VIII REGULATION (EU) 2017/746

Class C

Manufacturer and address of registered place of business

Manufacturer	Siemens Healthcare Diagnostics Products GmbH
Single Registration Number	DE-MF-000005039
Address	Emil-von-Behring-Str. 76 35041 Marburg Germany

Notified Body

Name	TÜV Rheinland LGA Products GmbH
Identification Number	0197
Address	Tillystr. 2 90431 Nürnberg Germany
Conformity Assessment Procedure	Annex IX

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): 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):	***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. CHIŞINĂU PENTRU FACTURI 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):***
Kontroll-Plasma N	*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]:*

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):*
Kontroll-Plasma P	*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 Amborn

Name /*Name*

2008-09-03

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

REPUBLICA MOLDOVA, mun. CHIŞINĂU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012000019..., 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]:*

REPUBLICA MOLDOVA I.C.S. «DIAMEDIA IMPEX» S.R.L. IDNO 1012600013981 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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):	***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*:

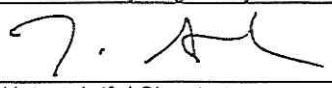
Sonstige	*Others*

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):	***Product name (English):***
Standard-Human-Plasma	*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*:

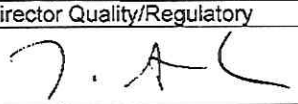
Sonstige	*Others*

Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	***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*
2011-04-05
Datum [JJJJ-MM-TT] / *Date [YYYY-MM-DD]:*