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):***
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

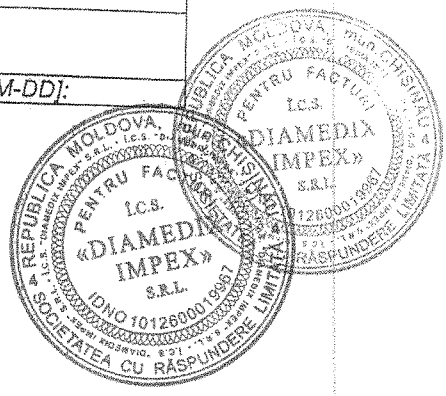
Unterschrift / *Signature*

Dr. Jörg Amborn

Name /*Name*

2008-09-03

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



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: [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

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:*

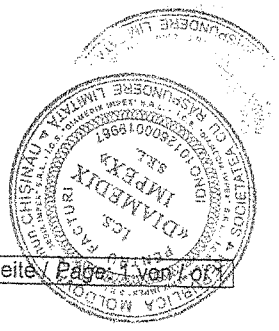
Siemens Healthcare Diagnostics Products GmbH

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):*
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:*

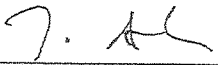
Sonstige	*Others*

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):	*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]:*

ICS «DIAMEDIX IMPEX» SRL

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

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

SIEMENS Healthineers

Siemens Healthcare Diagnostics Products GmbH, Marburg, Germany

Name Tobias Thäns
Department SHS LC LD ESB

Telephone +49 (6196) 7713-2414
Fax +49 (6196) 7713-7007

E-Mail tobias.thaens@siemens-healthineers.com

Our reference 21-0045
Date April 12, 2021

To whom it may concern
For presentation in
the Republic of Moldova

MANUFACTURER'S AUTHORIZATION

SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS GMBH a company incorporated and existing under the laws of the Federal Republic of Germany, with offices located at Emil-von-Behring-Strasse 76, 35041 Marburg, Germany (the "Company"), hereby acknowledges that it has designated **ICS Diamedix Impex SRL,** a company incorporated in the Republic of Moldova under the fiscal code (IDNO) 1012600019967 ("Representative") as an **AUTHORIZED REPRESENTATIVE** for the Republic of Moldova ("Territory"). As such Representative is duly authorized to register and re-register the products of the Siemens Healthineers in-vitro diagnostic portfolio (the "Products") listed in Attachment A within the Territory. The manufacturing facilities of the Company and its affiliates are listed in Attachment B.

In accordance with an Authorized Representative Agreement, Siemens Healthineers will, among other things, provide to the Representative such product-related technical documentation relevant to market surveillance investigations being undertaken by the Medicines and Medical Devices Agency in the Territory as may reasonably be required. In connection with the requirements of Annex 3 to the Administrative Procedures for Registration of medical devices nr. A07PS-01Rg04-112 dated 03.07.2014 ("Procedure Document"), however, we point out that the following information relating to the Products, to the extent not disclosed in documentation accompanying the Products (such as Instructions for Use) concerns trade secrets and/or binding confidentiality obligations (numbering reflects that of the Procedure Document):

3. Information on design and manufacturing
4. General requirements on safety and performance
5. Risk-benefit analysis and risk management
6. Verification and validation of product.

This Manufacturer's **AUTHORIZATION** does not confer any powers or authorizations beyond those contained herein. The present authorization should not be interpreted as an extension or renewal of any Authorized Representative Agreement or other contractual relationship. This letter of authorization shall remain valid until the process of registration ends or for **one year** from the date of this letter, whichever comes later, unless revoked sooner by the Company.

On behalf of Siemens Healthcare Diagnostics Products GmbH

Electronically signed by: Alexander Socarras
Reason: I am approving this document
Date: Apr 12, 2021 13:44 GMT+1

Name: A. Socarrás
Title: Executive Vice President Head of EMEA – Laboratory Diagnostics

Electronically signed by: Juergen Vogt
Reason: I have reviewed this document
Date: Apr 14, 2021 15:28 GMT+2

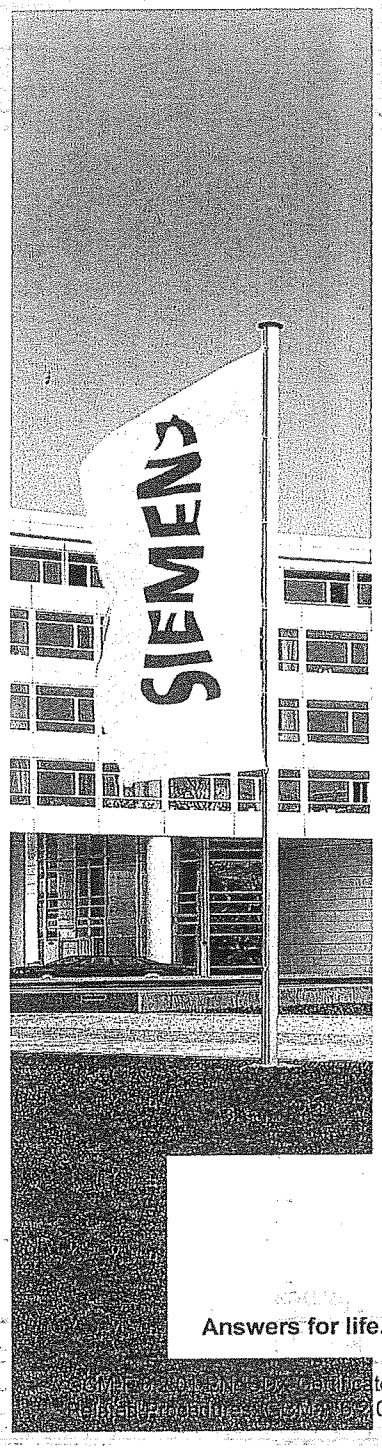
Name: Jürgen Vogt
Title: Authorized Representative

Attachment A– List of Products:

Automation Lines (StreamLab®, Workcell and Labcell)	Blood Gas
Clinical Chemistry (ADVIA® only)	Dimension – Dimension EXL, RXL Max, XPand Plus
Hematology	Hemostasis
Immunology (CENTAUR® and IMMULITE® lines)	Molecular Biology
Plasma Protein	Point of Care (DCA and Urine not including STRATUS ®)
Stratus CS Acute CARE	Urine
Viva line: V-Twin, Viva E, Viva jr (TDM and drugs)	Atellica Solution System and reagents and consumables

Attachment B– List of Affiliates and Manufacturing Facilities:

Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591-5097 USA	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin Ireland
Siemens Healthcare Diagnostics Manufacturing Ltd. Northern Road Chilton Industrial Estate Sudbury, Suffolk CO 10 2XQ United Kingdom	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd LL55 4EL United Kingdom
Siemens Healthcare Diagnostics Inc. 2 Edgewater Drive Norwood, MA 02062-4658 USA	Siemens Healthcare Diagnostics Inc. 3400 Middlebury Street Elkhart, IN 46516 USA
Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA 02032 USA	Siemens Healthcare Diagnostics Inc. 62 Flanders-Bartley Road Flanders, NJ 07836 USA
Siemens Healthcare Diagnostics Inc. 725 Potter Street Berkeley, CA 94710 USA	Siemens Healthcare Diagnostics Inc. 5210 Pacific Concourse Drive Los Angeles, CA 90045-6900 USA
Siemens Healthcare Diagnostics Inc. 115 Norwood Park South Norwood, MA 02062 USA	Siemens Healthcare Diagnostics Inc. 45764 Copco Avenue Gorman, California 93243 USA
Siemens Healthcare Diagnostics Inc. 500 GBC Dr., Mailstop 514 P.O. Box 6101 Newark, DE 19714 USA	Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Strasse 76 35041 Marburg Germany
Siemens Healthcare Diagnostics Inc. 430 S. Beiger Street Mishawaka, Indiana 46544 USA	Siemens Healthcare Diagnostics Inc. 101 Silvermine Road Brookfield, CT 06804 USA
Epocal Inc. (a Siemens Healthineers company) 2060 Walkley Road Ottawa K1G 3P5 Canada	Fast Track Diagnostics Luxemburg sarl (a Siemens Healthineers company) 29 rue Henri Koch Esch-sur-Alzette 4354 Luxembourg



Certificate

Mr Laurentiu Sauciuc

In recognition of your commitment to continuous learning and professional development you have completed:

Sysmex® CA 500 Series Application Training Course

from April 20th to 21st, 2010

Theodoris Desipris
Instructor

Answers for life.

SIEMENS