



Sysmex Europe SE · Bornbarch 1 · 22848 Norderstedt · Germany

To whom it may concern

Sysmex Europe SE
Bornbarch 1
22848 Norderstedt, Germany
Phone +49 40 527 26-0
Fax +49 40 527 26-100
info@sysmex-europe.com

LETTER OF AUTHORIZATION

Whereas Sysmex Europe SE ("Sysmex"), who are established, reputable and authorised representative in Europe, Africa and Middle East (EMEA region), officially announced by Sysmex Corporation, Japan,

as manufacturer for **Sysmex Coagulation Analyser** with Reagents, Accessories, Software and spare parts and as authorised distributor for **Siemens Coagulation Reagents** in the territory of Moldova (together the "Products")

do hereby declare that the company

ECHIPAMED Plus SRL
Valea Trandafirilor 24 "B", off. 80
MD-2001 Chisinau, Moldova (the "COMPANY")

is the non-exclusive distributor of the "Products" in the territory of Moldova.

This declaration is valid until 31 March 2023 and may be revoked unilaterally by Sysmex in writing before that date for due cause. Such due cause shall, among others, be the termination or expiration of the distributorship relationship, if any, between Sysmex and the Company.

On behalf of Sysmex Europe SE

Date: 10 June 2022

Place: 22848 Norderstedt, Germany

Matthias Voelkel
Senior Executive Officer



Sysmex Europe SE
Bornbarch 1
22848 Norderstedt

Company Location Norderstedt
Registered AG Kiel
HRB 24262 KI
VAT-ID DE 118 687 842
WEEE/ElektroG Reg. Nr. DE 159 56 453

Chairman of the
Supervisory Board:
Iwane Matsui

Management Board:
Alain Bayerel (CEO)
Alberto Bonacini
Yuki Hyogu
Stefanie Schaal
Matthias Völkel

COMMERZBANK AG, Hamburg
IBAN DE20 2004 0000 0287 1879 00
SWIFT/BIC Code COBADEFFXXX



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **09 100 89004**

Certificate Holder: **SYSMEX CORPORATION**
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
including the locations according to annex

Scope: Development, design, production, sales and servicing of in-vitro diagnostic medical devices, laboratory equipment, reagents and laboratory information system, and development, design, production and sales of customized recombinant protein

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-05-13 until 2024-07-31.
First certification 1998

2022-05-13

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com



Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1254782-1
Organization: **SYSMEX CORPORATION**
1-5-1 Wakinohama-Kaigandori,
Chuo-ku, Kobe
651-0073 Japan

Scope: Design and development, manufacture, distribution, installation and service of blood analyzer, urine analyzer, related reagents and accessories
Product categories: analyzers and reagents for hematological test, blood coagulation test, immune serum test, biochemical test, genetic test, bacteriological test and urine test

In accordance with EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150258788-301
Effective date: 2022-04-28
Expiry date: 2024-07-31
Issue date: 2022-04-28



M. Aihara



Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **09 104 9374**

Certificate Holder: **SYSMEX CORPORATION**
1-5-1 Wakinohama-kaigandori, Chuo-ku, Kobe
651-0073, Japan

including the locations according to annex

Scope: Development, Design, Production, Sales and Servicing Support of In-vitro Diagnostic Medical Devices, Laboratory Equipment, Reagents and Information Technology Systems for Laboratories and Sales of Customized Recombinant Proteins

Proof has been furnished by means of an audit that the requirements of ISO 14001:2015 are met.

Validity: The certificate is valid from 2020-04-07 until 2023-04-06.
First certification 2000

2020-02-25



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

EU Declaration of Conformity

Product identification:

Product name:	CA CLEAN I
Model name:	N/A
REF code:	964-0631-3
BUDI-DI:	4987562CACLEANI6U
Intended Purpose	See attachment.

Manufacturer:

Name:	SYSMEX CORPORATION
Single Registration Number:	JP-MF-000014037
Address:	1-5-1 Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan

Authorised representative:

Name:	SYSMEX EUROPE SE
Single Registration Number:	DE-AR-000022333
Address:	Bornbarch 1, 22848 Norderstedt, Germany

SYSMEX CORPORATION, as the manufacturer of the device, take sole responsibility for and hereby declare that the above mentioned device meets the provisions of the following Regulation:

- Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices
 Other Regulation(s)/Directive(s) as applicable for the device(s):

Risk class:


- A B C D

Conformity route:

Annex I+II+III according to Article 48 (10) of EU 2017/746

Common Specification:

N/A

	<i>Kobe Japan</i>	<i>25/01/2022</i>
Takashi Demachi	Name	Date
Executive Vice President	Function	(DD.MM.YYYY)

Sysmex Corporation

1-5-1 Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Tel 81-78-265-0500 Fax 81-78-265-0524



www.sysmex.co.jp

EU Declaration of Conformity

Product identification:

Product name:	CA CLEAN II
Model name:	N/A
REF code:	96406136, 974-0581-0, CJ038739
BUDI-DI:	4987562CACLEANIIG6
Intended Purpose	See attachment

Manufacturer:

Name:	SYSMEX CORPORATION
Single Registration Number:	JP-MF-000014037
Address:	1-5-1 Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan

Authorised representative:

Name:	SYSMEX EUROPE SE
Single Registration Number:	DE-AR-000022333
Address:	Bornbarch 1, 22848 Norderstedt, Germany

SYSMEX CORPORATION, as the manufacturer of the device, take sole responsibility for and hereby declare that the above mentioned device meets the provisions of the following Regulation:

- Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices
 Other Regulation(s)/Directive(s) as applicable for the device(s):

Risk class:

- A B C D

Conformity route:

Annex I+II+III according to Article 48 (10) of EU 2017/746

Common Specification:

N/A

<u>Takashi Demachi</u>	<u>Kobe Japan</u>	<u>24/05/2022</u>
Takashi Demachi	Place	Date
Executive Vice President	Function	(DD.MM.YYYY)

System Corporation





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, Executive Vice President

Date: 13 March 2018

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:


Fernando Andreu, Chief Operations Officer

Date: 14 March 2018

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.



To whom it may concern



Konformitätserklärung / Declaration of Conformity

Konformitätserklärung für Siemens Healthcare Diagnostics Products GmbH CE-markierte Produkte.

Hiermit erklären wir, dass ein Konformitätsbeurteilungsverfahren für die hier aufgelisteten In-vitro-Diagnostika-Produkte durchgeführt wurde und sie 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.

Declaration of Conformity for Siemens Healthcare Diagnostics Products GmbH CE-marked products.

We hereby declare that a conformity assessment has been performed for the in vitro diagnostic devices listed in the attachment and that they conform 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.

IVD-Kategorie / IVD category:

Sonstige	Others
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Legal Hersteller / Legal Manufacturer:

Siemens Healthcare Diagnostics Products GmbH
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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
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Mit freundlichen Grüßen,

Sincerely,

Siemens Healthcare Diagnostics Products GmbH

Christian Hainer
Regulatory Affairs Manager

Simone Biek
Regulatory Affairs Professional

Datum /Date: 2019-09-17

Anhang /Enclosure: Product List

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany



Konformitätserklärung

Declaration of Conformity

Enclosure to Certification, dd. 2019-09-17

Produktliste /Product List

Product Number (REF)	Package Size	Product Name (English)
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Hemostasis

281007		Thromboclotin
291070		Dade Ci-Trol 1
291071		Dade Ci-Trol 2
291072		Dade Ci-Trol 3
B4212-40, -50, -100		Dade Innovin
B4218-1, -2		Dade Actin Activated Cephaloplastin Reagent
B4218-20, -100		Dade Actin FS Activated PTT Reagent
B4219-1, -2		Dade Actin FSL Activated PTT Reagent
B4224-50		Dade Ci-Trol Heparin Control, Low
B4224-60		Dade Ci-Trol Heparin Control, High
B4233-15SY		Dade Fibrinogen Determination Reagents
B4233-22		Dade Data-Fi Abnormal Fibrinogen Control
B4233-25, -27		Dade Thrombin Reagent
B4234-25		Dade Owren's Veronal Buffer
B4238-40		Factor VIII Chromogenic Assay
B4244-10		Dade Ci-Trol Coagulation Control Level 1
B4244-20		Dade Ci-Trol Coagulation Control Level 2
OPAB	03	vWF Ag
OPAP	03	Protein S Ac
OPAT	03	PT-Multi Calibrator
OPBC	03	ProC Ac R
OPBP	03, 07	INNOVANCE D-Dimer
OPBR	03	INNOVANCE D-Dimer Sample Diluent
OPDY	03	INNOVANCE D-Dimer Controls
OPFH	03, 05	INNOVANCE Antithrombin
OPHL	03	INNOVANCE VWF Ac
OQAA	33	Imidazole Buffer Solution
OQAB	45	Kaolin Suspension
OQGP	17	LA 1 Screening Reagent
OQGR	13	LA 2 Confirmation Reagent
OQGS	29, 35	Pathromtin SL
OQKE	17	ProC Control Plasma
OQLS	13	ProC Global
OQVK	11	Fibrinogen Calibrator Kit
OQWD	11	LA Control High



Konformitätserklärung

Declaration of Conformity

Enclosure to Certification, dd. 2019-09-17

OQWE	11	LA Control Low
OQYG	11	Protein C Reagent
ORHO	37	Calcium Chloride Solution
ORKE	41	Control Plasma N
ORKL	17	Standard Human Plasma
ORSM	19	Coagulation Factor V Deficient Plasma
OSDF	13	Coagulation Factor XI Deficient Plasma
OSDG	13	Coagulation Factor XII Deficient Plasma
OSGR	13	Coagulation Factor II Deficient Plasma
OTXV	13	Coagulation Factor VII Deficient Plasma
OTXW	17	Coagulation Factor VIII Deficient Plasma
OTXX	17	Coagulation Factor IX Deficient Plasma
OTXY	13	Coagulation Factor X Deficient Plasma
OUBD 23		Von Willebrand Reagent
OUBD 37		BC von Willebrand Reagent
OUBU	15	Berichrom α_2 -Antiplasmin
OUCA	17	Berichrom Plasminogen
OUHP	29, 49	Thromborel S
OUIA	15	Berichrom C1-Inhibitor
OUPZ	17	Control Plasma P
OUVV	15	Berichrom Protein C
OWHM	13	Test Thrombin Reagent
OWNA	11	BC Thrombin Reagent
OWOA	15	Berichrom PAI
OWSU	11	Berichrom F XIII
OWWR	15, 17	Berichrom Antithrombin III (A)
OWZG	19, 23	Multifibren U

- End of Product List -





Zhejiang SKG Medical Technology Co., Ltd

Add: No.39, Anye Road, Gaoqiao Street, Huangyan, Taizhou, Zhejiang, China, 318020

Tel: 0086-576-84031666 Fax: 0086-576-84036668 Http://www.skgmed.com

CE Declaration of Conformity

Manufacturer: Zhejiang SKG Medical Technology Co., Ltd.

NO.39 Anye Road, Gaoqiao Street, Huangyan 318020 Taizhou, Zhejiang

PEOPLE'S REPUBLIC OF CHINA

European

Representative: Shanghai International Holding corp.GmbH(Europe)

Eiffestrabe 80 20537 Hamburg GERMANY

Product Name: Sample Cup

Model Number: BS-200, 700

Classification (IVDD): Other

Conformity Assessment Route: IVDD Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied:

ISO13485:2003, ISO11135-1:2007, ISO14971:2007, ISO 15223-1:2012

Notified Body: TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65·80339

München Germany

Identification number: Not applicable

(EC) Certificate(s): Not applicable

Expire date of the Certificate: Not applicable

Start of CE Marking: Not yet

Place, Date of Issue: HuangYan 2021-12-17

Signature: 

Name: Sujian

Position: General Manager

