Digitally signed by Iurchevici Valeriu
Date: 2026.03.20 10:29:57 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

sysmex

Sysmex Europe SE · Bornbarch 1 · 22848 Norderstedt · Germany

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

To whom it may concern

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.

The **COMPANY** is therefore authorized to carry out all commercial and support activities for the **PRODUCTS** including sales, marketing, application, registration and field service support in the **TERRITORY**.

This declaration is valid until 31 March 2026 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: March 17, 2025
Place: 22848 Norderstedt, Germany

sysmex
Sysmex Europe SE
Bornbarch 1
22848 Norderstedt

Matthias Voelkel
Senior Executive Officer
Member of Management Board

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 Baverel (CEO)
Yuki Hyogu
Dr Sanjeev Kumar
Stefanie Schaal
Matthias Voelkel

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

www.sysmex-europe.com

REPUBLICA MOLDOVA mun. CHIȘINĂU. SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600077671

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, laboratory information system and gene variants analysis set(for cancer genome profiling)

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

Validity: The certificate is valid from 2024-08-01 until 2027-07-31.
First certification 1998

2024-07-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 1254782-1
Certificate Holder:	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 and gene variants analysis set (for cancer genome profiling) Product categories: Analyzers and reagents for hematological test, blood coagulation test, immune serum test, biochemical test, genetic test, bacteriological test and urine test Installation is not applicable for reagents and gene variants analysis set (for cancer genome profiling) 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.:	150287325-301
Effective date:	2024-08-01
Expiry date:	2027-07-31
Issue date:	2024-07-04

Replaces certificate SX 1254782-1 issued 2023-08-28

Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

Company Version: n/a
Version Approval Date: 05-Jul-2024

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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 Wakinohama-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

Takashi Demachi	Kobe Japan	24/01/2022
Name Executive Vice President	Place Function	Date (DD.MM.YYYY)

sysmex
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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 Wakinohama-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

Takashi Demachi	Kobe Japan	24/04/2022
Takashi Demachi Executive Vice President	Name Function	Place	Date (DD.MM.YYYY)

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 Date: 13 March, 2018
Hiroshi Yamane, Executive Vice President

Authorised representative:

Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Date: MARCH 21ST 2018
Fernando Andreu, Chief Operations Officer

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.

Sysmex Corporation
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Tel. +81-78-265-0500 Fax. +81-78-265-0524
www.sysmex.co.jp

SIEMENS Healthineers

To whom it may concern

CE

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*

Legaler Hersteller / ***Legal 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*

Mit freundlichen Grüßen,

Sincerely,

Siemens Healthcare Diagnostics Products GmbH

i.V.

Christian Hainer
Regulatory Affairs Manager

i.A.

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

REPUBLICA MOLDOVA mun. CHIŞINĂU. SOCIETATEA CU RASPUNDERE LIMITATA "TEHNIPAMED-PLUS" IDNO 1003600077677

SIEMENS Healthineers

Konformitätserklärung

Declaration of Conformity

Enclosure to Certification, dd. 2019-09-17

Produktliste /*Product List*

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

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

SIEMENS Healthineers

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* -

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

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EU Declaration of Conformity

Product identification:

Product name:	AUTOMATED BLOOD COAGULATION ANALYZER
Model name:	CS-1600
REF code:	BQ203979
BUDI-DI:	4987562CS-1600P5
Intended Purpose	See attachment

Manufacturer:

Name:	SYSMEX CORPORATION
Single Registration Number:	JP-MF-000014037
Address:	1-5-1 Wakinohama-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 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):
  2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment and its related amending directives including the (EU)2015/863 amending Annex II of the Directive 2011/65/EU

Risk class:

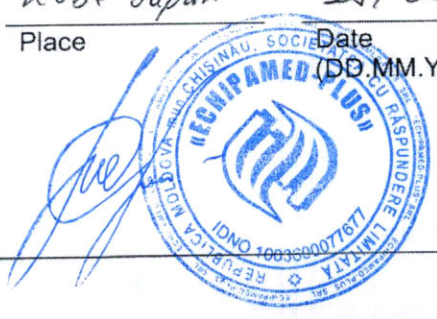
☒ A ☐ B ☐ C ☐ D

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

Common Specification:
N/A

Takashi Demachi — Name
Executive Vice President — Function

Kobe Japan — Place
24/04/2022 — Date (DD.MM.YYYY)



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 042464 0039 Rev. 00

Manufacturer:

Zhejiang Gongdong Medical Technology Co., Ltd.
No.10 Beiyuan Ave., Huangyan
318020 Taizhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000005694

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to establishing, securing and maintaining sterile conditions.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V11 042464 0039 Rev. 00

Report No.: SH2211102

Valid from: 2023-04-11

Valid until: 2028-04-10

Marta Carnielli
Head of Notified Body IVD

Issue date: 2023-04-11

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 042464 0039 Rev. 00

Classification:	Class A
Device Group:	W050101 - BLOOD COLLECTION DEVICES
Intended Purpose:	IVR 0803 - Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2023-04-11	SH2211102	Initial issuance

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600077677

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®