Digitally signed by Iurchevici Valeriu
Date: 2023.01.18 14:40:32 EET
Reason: MoldSign Signature
Location: Moldova

sysmex

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 the manufacturer *Sysmex* Corporation, having its principal place of business at 1-5-1 Wakinohama-Kaigandoori, Chuo-ku, Kobe 651-0073, Japan, and having the power to grant authorizations to local representatives within the above mentioned markets,

do hereby declare that the company

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

is our distributor and local representative for the following Sysmex products:

Sysmex Haematology- and Urine- Analysers
with Reagents, Accessories, Software and Spare Parts
(the "**Products**")

In the territory of Moldova (the "**TERRITORY**")

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**.

The **COMPANY** is aware that this special authorisation is limited to the above listed **PRODUCTS** and does not create any further rights for the **COMPANY**.
We hereby grant our warranty following our general conditions of sale for the **PRODUCTS** delivered, consisting of and limited to:
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

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

Sysmex Europe SE
Bornbarch 1
22848 Norderstedt

Matthias Voelkel
Senior Executive Officer

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

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

TÜVRheinland®
Precisely Right.

Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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

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

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

www.tuv.com

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

TÜVRheinland®
Precisely Right.

EC Declaration of Conformity

Application of Council Directive:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

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,
- Directive 2011/65/EU by drawing up the required technical documentation and carrying out the internal production control procedure in line with module A of Annex II to decision No 768/2008EC.

Product identification:

Product name:	Automated Hematology Analyzer XP series
Model name:	XP-100, XP-300
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: 23 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

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: Automated Hematology Analyzer XS series

Model: XS-1000i, XS-800i, XS-500i, XS-900i

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: Kohei Sumitani

Position: President

Date: 2013 July 29th

Place: Germany

This certificate was issued under sole responsibility of:

Authorised officer: Keiji Fujimoto

Position: Executive Officer

Date: 2013. July 24th.

Place: Japan

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

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: Automated Hematology Analyzer

Model: XT-2000i

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: 15/ AEc/ 2003

Place: Germany

This certificate was issued under sole responsibility of:

Authorised officer: Takuji Nishino

Position: Vice President, Technology Control

Date: December 9, 2003

Place: Japan

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

ACADEMY

sysmex

CERTIFICATE

Настоящий сертификат подтверждает, что

Овчиников Владимир Сергеевич,

сотрудник компании «Echipamed Plus» SRL,

прошел тренинг по программе:

«Базовый технический тренинг»

В рамках данной программы были изучены следующие вопросы:

- *Основы гематологии*
- *Принципы измерений*
- *Введение оборудования в эксплуатацию*
- *Настройка и калибровка*
- *Профилактическое обслуживание*
- *Устранение неисправностей*

Для анализаторов KX-21, KX-21N, pocH-100i, XP-300

30 августа 2017 г

[Овчиников В.С.]

ООО «Сисмекс РУС»

ECHIPAMED-PLUS

IDNO 1003600077677

Growing your knowledge. For life.

CERTIFICATE

sysmex

Certificate

Herewith we confirm

Igor Volosatov

the successful completion of the

XS Technical Training

from August 30th - Septemer 3rd, 2010
in Norderstedt, Germany

Theoretical knowledge, complemented with practical exercises, was given on the following subjects:

Installation
Adjustment
Maintanance
Troubleshooting

September 3rd, 2010
Date

Unterschrift Trainer
Sysmex Europe GmbH

Sysmex Academy

Certificate

is hereby granted to :

Igor Volosatov

for participation in and successful completion of

Sysmex XT-Series Technical Training

Norderstedt, May 19 – 23.2008

Stephan Behrens
Technical Product Manager
Sysmex Service Center

Sysmex

RECHIPAMED-PLUS