Digitally signed by Iurchevici Valeriu
Date: 2022.01.20 17:10:38 EET
Reason: MoldSign Signature
Location: Moldova

Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

To whom it may concern

Sysmex Europe GmbH
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 GmbH ("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 2022 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 GmbH

Jan-Willem Schipper
Senior Executive Officer

Date: 08 March, 2021
Place: 22848 Norderstedt, Germany

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info@sysmex-europe.com

LETTER OF AUTHORIZATION

Whereas Sysmex Europe GmbH ("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 2022 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 GmbH

Date: 08 March, 2021
Place: 22848 Norderstedt, Germany

Jan-Willem Schipper
Senior Executive Officer

Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt

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 2021-08-01 until 2022-01-31.
First certification 1998

2021-07-30

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

TÜVRheinland®
Precisely Right.

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

SYSMEX EUROPE GmbH
Bornbarch 1
22848 Norderstedt
Deutschland

has establisned and applies a quality management system for medical devices for the following scope:

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-05-17
Certificate Registration No.:	SX 60137613 0001
An audit was performed. Report No.:	21245244 005
This Certificate is valid until:	2022-05-16

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2019-04-29

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 110072**

Certificate Holder: **SYSMEX EUROPE GmbH**
Bornbarch 1
22848 Norderstedt
Germany

Scope: Sales, marketing and service of
in-vitro diagnostic medical devices

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

Validity: The certificate is valid from 2020-07-25 until 2023-07-24.
First certification 2011

2020-03-19

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

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:	Automated Hematology Analyzer XN series
System name:	XN-1000, XN-1500, XN-2000, XN-3000, XN-3100, XN-9000, XN-9100
Model name:	XN-10, XN-20, XN-11, XN-21, XN-20[A1], XN-20[A2], XN-10[B1], XN-10[B2], XN-10[B3], XN-10[B4]
Accessories:	SA-01, SA-10, SA-20, SA-21, SA-31, BT-40, CV-50, CV-55, CV-60, CV-65, CV-70, ST-40, ST-41, ST-42, TU-40, RR-10, SA-30, WG-17, WG-31, WG-40, WG-50, WG-55, WG-60, WG-65
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

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
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