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**.

Digitally signed by Iurchevici Valeriu
Date: 2021.01.27 17:20:23 EET
Reason: MoldSign Signature
Location: Moldova

«ECHIPAMED-PLUS»
IDNO 1003600077677
REPUBLICA MOLDOVA, MUNICIPIUL CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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 31.03.2021 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: March 20th, 2020
Place: 22848 Norderstedt, Germany

Jan-Willem Schipper
Senior Executive Officer

Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt

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

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

EC Declaration of Conformity

Application of Directives:

- 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 conformity assessment procedures in accordance with Annex III of the Directive.

Product identification:

Product name: CELLPACK DCL

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

EC Declaration of Conformity

Application of Directives:

- 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 conformity assessment procedures in accordance with Annex III of the Directive.

Product identification:

Product name:	SULFOLYSER
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: 3 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 Directives:

- 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 conformity assessment procedures in accordance with Annex III of the Directive.

Product identification:

Product name: Lysercell WDF

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

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EC Declaration of Conformity

Application of Directives:

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Means of conformity:

The following product is in conformity with
- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III of the Directive.

Product identification:

Product name: Fluorocell WDF

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

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www.sysmex.co.jp

EC Declaration of Conformity

Application of Directives:

- 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 conformity assessment procedures in accordance with Annex III of the Directive.

Product identification:

Product name: CELLCLEAN

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:

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Means of conformity:

The following product is in conformity with
- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III of the Directive.

Product identification:

Product name: XN CHECK

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

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"ECHIPAMED-PLUS" CHISINAU, SOCIETATEA CU RASPUNDERE LIMITATA REPUBLICA MOLDOVA mun. CHISINAU IDNO 1003600077[illegible]

Sysmex Corporation
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Application of Directives:

- 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 conformity assessment procedures in accordance with Annex III of the Directive.

Product identification:

Product name: XN CAL

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

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www.sysmex.co.jp

ACADEMY

sysmex

CERTIFICATE

CERTIFICATE

Serghei Costov

ECHIPAMED Plus SRL

has successfully completed the

XN-L Series Technical Training

in Norderstedt, Germany from March 7 to March 11, 2016

Product informations / specifications
Haematology
Installation
Quality control
Sensitivity adjustment and calibration
Hydraulics / pneumatics / electronics / software
Maintenance & troubleshooting

Sysmex Europe GmbH · Norderstedt, Germany · March 11, 2016

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