



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 Wakino-hama-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**.

Company Location Norderstedt
Registered AG Kiel
HRB 4179
VAT-ID DE 118 687 842
WEEE/ElektroG Reg. Nr. DE 159 56 453

Managing Directors
Alain Baverel
Seido Biwa
Alberto Bonacini
Kensuke Iizuka
Iwane Matsui
Stefanie Schaal
Jan Willem Schipper
Matthias Völkel

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





We hereby grant our warranty following our general conditions of sale for the **PRODUCTS** delivered, consisting of and limited to:

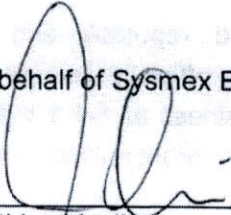
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

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 GmbH

Date: 09 February, 2022

Place: 22848 Norderstedt, Germany


Matthias Voelkel
Senior Executive Officer



Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt



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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

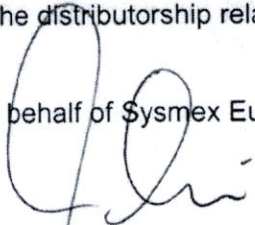
ECHIPAMED Plus SRL
Valea Trandafirilor 24 "B", off. 80
MD-2001 Chisinau, Moldova (the "COMPANY")

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

This declaration is valid until 31 March 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 GmbH

Date: 09 February, 2022
Place: 22848 Norderstedt, Germany


Matthias Voelkel
Senior Executive Officer



Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt


Company Location Norderstedt
Registered AG Kiel
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VAT-ID DE 118 687 842
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Managing Directors
Alain Baverel
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Iwane Matsui
Stefanie Schaal
Jan Willem Schipper
Matthias Voelkel

COMMERZBANK AG, Hamburg
IBAN DE20 2004 0000 0287 1379 00
SWIFT/BIC Code COBADEFFXXX



Certificate

Standard **ISO 14001:2015**

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

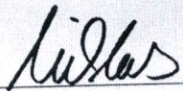
Certificate Holder: **SYSMEX EUROPE GmbH**
Bornbarch 1
22848 Norderstedt
Germany

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



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 Wakino-hama-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: Fernando Andreu 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.



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.
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Product identification:

Product name: Automated Blood Coagulation Analyzer CS-2100i
Model name: CS-2100i
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:  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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