

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 Bonadini
Kensuke Iizuka
Iwane Matsui
Stefanie Schaal
Jan Willem Schipper
Matthias Völkel

COMMERZBANK AG, Hamburg
IBAN DE20 2004 0000 0287 1879 00
SWIFT/BIC Code COBADE33XXX

www.sysmex-europe.com





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

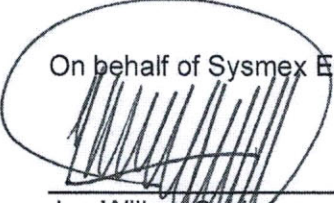
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

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



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
SYSMEX EUROPE GmbH
Bornbarch 1
22848 Norderstedt
Deutschland

has established 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



Date 2019-04-29

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>



S. Hoffmann
Dipl.-Ing. Sven Hoffmann

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

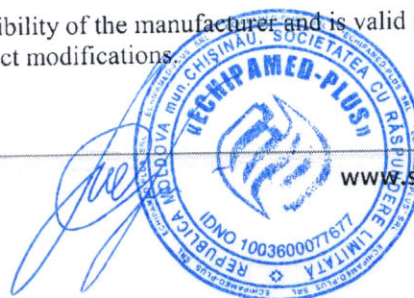
Authorised officer: Hiroshi Yamane Date: 13 March 2018
Hiroshi Yamane, Executive Vice President

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

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



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

