



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**.



Company Location Norderstedt
Registered AG Kiel
HRB 4179
VAT-ID DE 118 687 842
WEEF/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 COBADEFFXXX

www.sysmex-europe.com





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

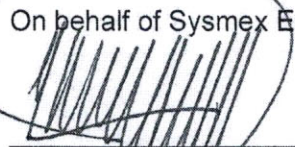
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

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



Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 110072

Certificate Holder:



SYSMEX EUROPE GmbH

Bornbarch 1
22848 Norderstedt
Germany

including the locations according to annex

Scope:

Sales and service of devices, reagents and accessories for in-vitro diagnostics in the area of haematology, urine analytics, coagulation and detection of an epithelial cell marker for the diagnosis of metastases in lymph nodes, as well as of products in the area of laboratory automation and laboratory EDP systems. Design, development and manufacturing of software for in-vitro diagnostic use. Distribution of magnetic sensing devices, probes, associated equipment and sterile magnetic markers. Distribution and servicing of scalp-cooling devices with accessories.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2018-09-06 until 2020-07-24.
First certification 2011

2018-09-13

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln



www.tuv.com



Deutsche
Akkreditierungsstelle
D-ZM-16031-01-00



TÜVRheinland®
Precisely Right.



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.

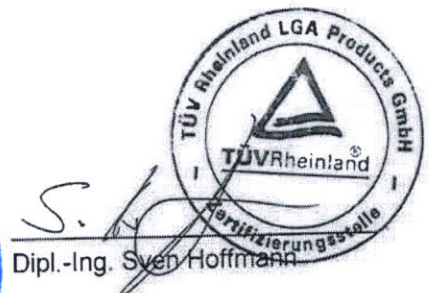
Effective Date: 2019-05-17
Certificate Registration No.: SX 60137613 0001
An audit was performed. Report No.: 21245244 005
This Certificate is valid until: 2022-05-16

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

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: 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.

