

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 116 687 842  
WEEE/ElektroG Reg. Nr. DE 159 56 459

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

COMMERZBANK AG, Hamburg  
IBAN DE 20 2004 0000 0287 1879 00  
SWIFT/BIC Code COBADE33XXX

[www.sysmex-europe.com](http://www.sysmex-europe.com)





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

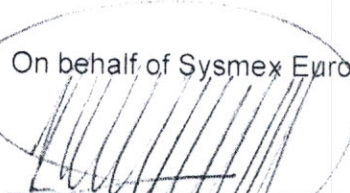
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

This declaration is valid until 31 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

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.

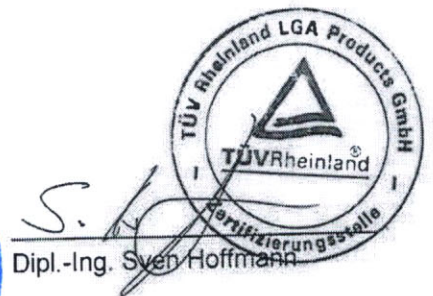
Effective Date: 2019-05-17  
Certificate Registration No.: SX 60137613 0001  
An audit was performed. Report No.: 21245244 005  
This Certificate is valid until: 2022-05-16

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 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: Bornbarck 1, 22848 Norderstedt, Germany

Authorised officer: Fernando Andreu Date: MARCH 21<sup>ST</sup> 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.

