

To whom it may concern

## 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

### **ECHIPAMED Plus SRL,**

Valea Trandafirilor 24 «B», off. 80, MD-2001 Chisinau, Moldova is our distributor and local representative in the territory of Republic of Moldova (the "**COMPANY**")

for the following Sysmex products:

### **Sysmex Haematology- and Urine Analysers**

Reagents, Accessories, Software and spare parts (the "**PRODUCTS**").

in the territory of Republic 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**.

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

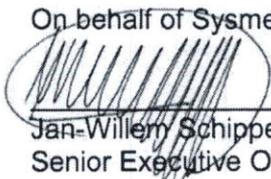
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

This declaration is valid until 31.03.2019 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 28<sup>th</sup>, 2018

Place: DE-22848 Norderstedt

  
Jan-Willem Schipper  
Senior Executive Officer

  
Sysmex Europe GmbH

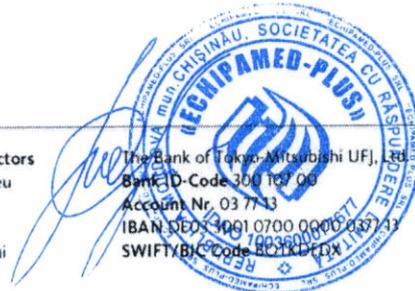


**Sysmex Europe GmbH**  
Bornbarch 1, 22848 Norderstedt  
Phone +49 40 52726-0  
Fax +49 40 52726-100  
www.sysmex-europe.com

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

**Managing Directors**  
Fernando Andreu  
Alain Baverel  
Seido Biwa  
Alberto Bonacini  
Kensuke Iizuka  
Kazuya Obe  
Jan-Willem Schipper  
Dr. Jürgen Schulze  
Matthias Völkel

The Bank of Tokyo-Mitsubishi UFJ, Ltd. Hamburg  
Bank ID-Code 300 107 000  
Account Nr. 03 77 13  
IBAN DE03 3001 0700 0000 0377 13  
SWIFT/BIC Code BKTW3333



# 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

# 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:

**Details see attachment**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012**  
**EN ISO 13485:2012/AC:2012**

are fulfilled. The quality management system is subject to yearly surveillance.

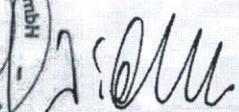
Effective Date: 2016-05-17  
Certificate Registration No.: SX 60109566 0001  
An audit was performed. Report No.: 21245244 002  
This Certificate is valid until: 2019-05-16

Certification Body



Date 2016-05-17



  
Dipl.-Ing. C. Wiora

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert.validation@de.tuv.com http://www.tuv.com/safety

# 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: KX-21N

**Manufacturer:**

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073

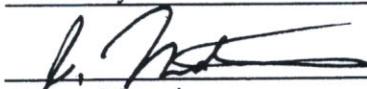
Country: Japan

**Authorised representative:**

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt

Country: Germany

Authorised officer: 

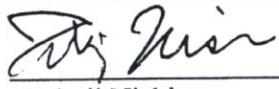
Iwane Matsui

Position: President

Date: 30TH SEPTEMBER 2003

Place: Germany

This certificate was issued under sole responsibility of:

Authorised officer: 

Takuji Nishino

Position: Vice President, Technology Control

Date: 24. Sep. 2003

Place: Japan

