



Sysmex Europe GmbH Bornbarch 1 · 22848 Norderstedt Germany

To whom it may concern

Sysmex Europe GmbH  
Bornbarch 1  
22848 Norderstedt, Germany  
Phone +49 40 52726-0  
Fax +49 40 52726-100  
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 Wakinochama 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 (the "**COMPANY**")

is our distributor and local representative 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 31.03.2020 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

Jan-Willem Schipper  
Senior Executive Officer

  
**sysmex**

Sysmex Europe GmbH  
Bornbarch 1  
22848 Norderstedt

Date: April 16, 2019  
Place: 22848 Norderstedt

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 Itzuka  
Kazuya Obe  
Jan-Willem Schipper  
Matthias Völkel

MUFG Bank (Europe) N.V. Hamburg  
Bank ID-Code 300 107 00  
Account Nr. 03 77 13  
IBAN DE03 3001 0700 0000 0377 13  
SWIFT/BIC Code BOTKDE33





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## LETTER OF AUTHORISATION

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**")

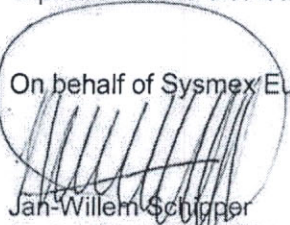
do hereby declare that the company

**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 31.03.2020 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

  
Jan-Willem Schipper  
Senior Executive Officer



Sysmex Europe GmbH

Date: March 13<sup>th</sup>, 2019  
Place: 22848 Norderstedt

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  
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IBAN DE03 3001 0700 0000 0377 13  
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# 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



# Certificate

Standard **ISO 14001:2015**

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

Certificate Holder:



**SYSMEX EUROPE GmbH**

Bornbarch 1  
22848 Norderstedt  
Germany

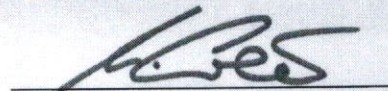
including the location  
**Sysmex Deutschland GmbH**  
Bornbarch 1  
22848 Norderstedt  
Germany

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 2017-07-25 until 2020-07-24.  
First certification 2011

2018-02-12



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

  
www.tuv.com



DAkkS  
Deutsche  
Akkreditierungsstelle  
D-ZM-16031-01-00



**TÜVRheinland®**  
Precisely Right.



# 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: CUVETTE

Model name: SUC-400A

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 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.

Sysmex Corporation

1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

Tel. +81-78-265-0500 Fax. +81-78-265-0524

*[Signature]*  
www.sysmex.co.jp



# EC Declaration of Conformity

## Application of Directives:

- 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 conformity assessment procedures in accordance with Annex III of the Directive.

## Product identification:

Product name: CA CLEAN I

Classification: Other device (except Annex II and self-testing devices)

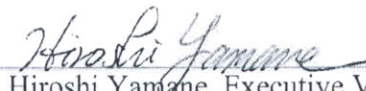
## List of Applied Standards:

- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

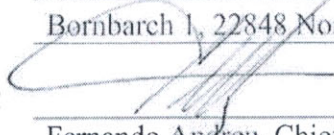
Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

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 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.







# EC Declaration of Conformity

## Application of Directives:

- 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 conformity assessment procedures in accordance with Annex III of the Directive.

## Product identification:

Product name: UX II SEARCH - SED

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*  
Hiroshi Yamane, Executive Vice President

Date: 13 March, 2018

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

*Fernando Andreu*  
Fernando Andreu, Chief Operations Officer

Date: MARCH 21ST 2018

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.