



Sysmex Europe SE · Bornbarch 1 · 22848 Norderstedt · Germany

To whom it may concern

Sysmex Europe SE  
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 SE ("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**.

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.

Company Location Norderstedt  
Registered AG Kiel  
HRB 24262 KI  
VAT-ID DE 118 687 842  
WEEE/ElektroG Reg. Nr. DE 159 56 453

Chairman of the  
Supervisory Board:  
Iwane Matsui

Management Board:  
Alain Baverel (CFO)  
Alberto Bonacini  
Yuki Hyogu  
Stefanie Schaal  
Matthias Völkel

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

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





This declaration is valid until 31 March 2024 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 SE

Matthias Voelkel  
Senior Executive Officer

Date: 08 March 2023  
Place: 22848 Norderstedt, Germany



Sysmex Europe SE  
Bornbarch 1  
22848 Norderstedt



# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **09 100 89004**

Certificate Holder: **SYSMEX CORPORATION**  
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan  
including the locations according to annex

Scope: Development, design, production, sales and servicing of in-vitro diagnostic medical devices, laboratory equipment, reagents and laboratory information system, and development, design, production and sales of customized recombinant protein

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

Validity: The certificate is valid from 2022-05-13 until 2024-07-31.  
First certification 1998

2022-05-13

TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

www.tuv.com



**TÜVRheinland®**  
Precisely Right.

# Certificate



Quality Management System  
EN ISO 13485:2016

Registration No.: SX 1254782-1  
Organization: SYSMEX CORPORATION  
1-5-1 Wakinohama-Kaigandori,  
Chuo-ku, Kobe  
651-0073 Japan

Scope: Design and development, manufacture, distribution, installation and service of blood analyzer, urine analyzer, related reagents and accessories  
Product categories: analyzers and reagents for hematological test, blood coagulation test, immune serum test, biochemical test, genetic test, bacteriological test and urine test

In accordance with EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150258788-301  
Effective date: 2022-04-28  
Expiry date: 2024-07-31  
Issue date: 2022-04-28



*M. Aihara*



Michiaki Aihara  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# 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

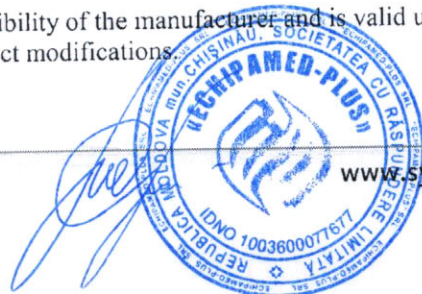
Authorised officer: Hiroshi Yamane Date: 13 March 2018  
Hiroshi Yamane, Executive Vice President

## Authorised representative:

Name: SYSMEX EUROPE GMBH  
Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Fernando Andreu Date: MARCH 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 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

## CERTIFICATE

Настоящий сертификат подтверждает, что

**Овчиников Владимир Сергеевич,**

сотрудник компании «Echipamed Plus» SRL,

прошел тренинг по программе:

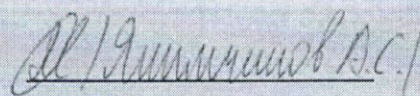
**«Базовый технический тренинг»**

В рамках данной программы были изучены следующие вопросы:

- *Основы гематологии*
- *Принципы измерений*
- *Введение оборудования в эксплуатацию*
- *Настройка и калибровка*
- *Профилактическое обслуживание*
- *Устранение неисправностей*

Для анализаторов KX-21, KX-21N, роSH-100i, XP-300

30 августа 2017 г



ООО «Сисмекс РУС»



# Certificate

Herewith we confirm

Igor Volosatov

the successful completion of the

## XS Technical Training

from August 30th - September 3rd, 2010  
in Norderstedt, Germany

Theoretical knowledge, complemented with practical exercises,  
was given on the following subjects:

- Installation
- Adjustment
- Maintenance
- Troubleshooting

September 3rd, 2010

Date



  
Unterschrift Trainer  
Sysmex Europe GmbH

Systemex  
Academy



# Certificate

is hereby granted to :

**Igor Volosatov**

for participation in and successful completion of

**Sysmex XT-Series  
Technical Training**

Norderstedt, May 19 – 23.2008



Stephan Behrens  
Technical Product Manager  
Sysmex Service Center

**Systemex**

