

Sysmex Europe SE - Bornbarch 1 - 22848 Norderstedt - Germany

To whom it may concern

Sysmex Europe SE
Bornbarch 1
22848 Norderstedt, Germany
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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 COMMERZBANK AG, Hamburg IBAN DE20 2004 0000 0287 1879 00 SWIFT/BIC Code COBADEFFXXX

www.sysmex-europe.com

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



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

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

Missas

TÜV Rheinland Cert GmbH Am Grauen Stein · 51105 Köln





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

TÜVRheinland

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

Dakks
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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

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EC Declaration of Conformity

Application of Council	Directive:
- 98/79/EC of 27 Octob	per 1998 on In Vitro Diagnostic Medical Devices.
0.1	s are in conformity with assed on the conformity assessment procedures in accordance with
Product identification:	
Product name:	MEDITAPE UC-9A, MEDITAPE UC-11A, MEDITAPE UC-10S, MEDITAPE UC-12S
Classification:	Other device (except Annex II and self-testing devices)
- Harmonised Standard documentation. Legal Manufacturer:	s used for conformity assessment are listed in the technical
Name:	SYSMEX CORPORATION
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
Authorised officer:	Takashi Demachi, Executive Vice President
Authorised representati	tive:
Name:	SYSMEX EUROPE SE
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer	Date: 28.04.202

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until the end of transitional period stipulated in REGULATION (EU) 2017/746 & its related regulations. The Classification of this product under REGULATION (EU) 2017/746 is Class B.

Quality Assurance, Quality Control

Sinem Yaman, Vice President, Head of Regulatory Affairs,

www.sysmex.co.jp



EC Declaration of Conformity

Application	of Council	Directive:
Application	of Council	Directive.

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices.

Means	of	conf	form	ity:
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The following products are in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III.

		110			
Product	ICI	Antiti	Cal	inn'	•
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Product name:

UC-CONTROL

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:

Takashi Demachi, Executive Vice President

Authorised representative:

Name:

SYSMEX EUROPE SE

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Sinem Yamen, Vice President, Head of Regulatory Affairs.

Date:

Quality Assurance, Quality Control

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until the end of transitional period stipulated in REGULATION (EU) 2017/746 & its related regulations. The

Classification of this product under REGULATION (EU) 2017/746 is Class B.

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