

Sysmex Europe SE · Bornbarch 1 · 22848 Norderstedt · Germany

To whom it may concern

Sysmex Europe SE
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#### 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 (CEO) 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





This declaration is valid until 31 March 2023 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

Date: 10 June 2022

Place: 22848 Norderstedt, Germany

sysmex

Matthias Voelkel Senior Executive Officer Sysmex Europe SE Bornbarch 1 22848 Norderstedt

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## 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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# Certificate

Standard

ISO 14001:2015

Certificate Registr. No.

09 104 9374

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 Support of In-vitro Diagnostic Medical Devices, Laboratory Equipment, Reagents and Information Technology Systems for Laboratories and Sales of Customized Recombinant Proteins

Proof has been furnished by means of an audit that the requirements of ISO 14001:2015 are met.

Validity:

The certificate is valid from 2020-04-07 until 2023-04-06. First certification 2000

2020-02-25

Trella .

TÜV Rheinland Cert GmbH Am Grauen Stein · 51105 Köln

TAF

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

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