



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 (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



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.

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: MEDITAPE UC-9A, MEDITAPE UC-11A, MEDITAPE UC-10S,
MEDITAPE UC-12S

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 Date: Apr. 28, 2022
Takashi Demachi, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE SE

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Sinem Yaman Date: 28.04.2022
Sinem Yaman, Vice President, Head of Regulatory Affairs,
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.

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: 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 Wakinoama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan

Authorised officer: Takashi Demachi Date: Apr. 28, 2022
Takashi Demachi, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE SE

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: [Signature] Date: 28.04.2022
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