Digitally signed by Iurchevici Valeriu
Date: 2024.11.19 16:11:51 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

sysmex

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:



REPUBLICA MOLDOVA mun. CHIȘINĂU. SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS» IDNO 1003600077677

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 March 2025 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: March 4, 2024
Place: 22848 Norderstedt, Germany

Matthias Voelkel
Senior Executive Officer
Member of Management Board

Sysmex Europe SE
Bornbarch 1
22848 Norderstedt

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TECHIPAMED-PLUS" IDNO 1003600077677

# 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, laboratory information system and gene variants analysis set(for cancer genome profiling)

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

Validity: The certificate is valid from 2024-08-01 until 2027-07-31.
First certification 1998

2024-07-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

TÜVRheinland®
Precisely Right.

# Certificate

## Quality Management System
## EN ISO 13485:2016

| | |
|---|---|
| Registration No.: | SX 1254782-1 |
| Certificate Holder: | SYSMEX CORPORATION<br>1-5-1 Wakinohama-Kaigandori,<br>Chuo-ku, Kobe<br>651-0073 Japan |
| Scope: | Design and development, manufacture, distribution, installation and service of blood analyzer, urine analyzer, related reagents and accessories and gene variants analysis set (for cancer genome profiling)<br>Product categories: Analyzers and reagents for hematological test, blood coagulation test, immune serum test, biochemical test, genetic test, bacteriological test and urine test<br><br>Installation is not applicable for reagents and gene variants analysis set (for cancer genome profiling)<br><br>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.: | 150287325-301 |
| Effective date: | 2024-08-01 |
| Expiry date: | 2027-07-31 |
| Issue date: | 2024-07-04 |

Replaces certificate SX 1254782-1 issued 2023-08-28

Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com





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

TÜVRheinland®
Precisely Right.

Company Version: n/a
Version Approval Date: 05-Jul-2024

sysmex
Lighting the way with diagnostics

# EU Declaration of Conformity

Product identification:

| | |
|---|---|
| Product name: | CELLCLEAN |
| Model name: | N/A |
| REF code: | 834-0162-1, BU037001 |
| BUDI-DI: | 4987562CELLCLEANP7 |
| Intended Purpose | See attachment |

Manufacturer:

| | |
|---|---|
| Name: | SYSMEX CORPORATION |
| Single Registration Number: | JP-MF-000014037 |
| Address: | 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan |

Authorised representative:

| | |
|---|---|
| Name: | SYSMEX EUROPE SE |
| Single Registration Number: | DE-AR-000022333 |
| Address: | Bornbarch 1, 22848 Norderstedt, Germany |

SYSMEX CORPORATION, as the manufacturer of the device, take sole responsibility for and hereby declare that the above mentioned device meets the provisions of the following Regulation:

☒ Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices

☐ Other Regulation(s)/Directive(s) as applicable for the device(s):

Risk class:

☒ A ☐ B ☐ C ☐ D

Conformity route:
Annex I+II+III according to Article 48 (10) of EU 2017/746

Common Specification:
N/A

| Takashi Demachi | Kobe Japan | 24/Oct/2022 |
|---|---|---|
| Takashi Demachi<br>Executive Vice President | Name<br>Function | Place | Date<br>(DD.MM.YYYY) |