



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:

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)  
Yuki Hyogu  
Stefanie Schaal  
Matthias Voelkel

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

www.sysmex-europe.com





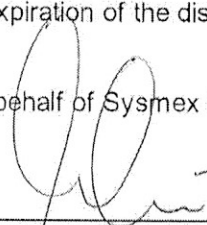
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

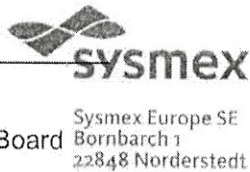
This declaration is valid until 31 March 2025 and may be revoked unilaterally by Sysmex in writing before that date for due cause. Such due cause shall, among others, be the termination or expiration of the distributorship relationship, if any, between Sysmex and the **COMPANY**.

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 · 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

## DECLARATION

We, Sysmex Europe SE, located at Bornbarch 1, 22848 Norderstedt, Germany, who are established, reputable and authorized representatives in Europe (EC REP), 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

hereby confirm that the following analyzers:

- Automated Hematology Analyser XN-L series, model XN-330, XN-350, XN-530, XN-550
- Automated Hematology Analyser XN series, XN-1000, XN-2000
- Automated Hematology Analyser XP series, model XP-300
- XR-Series Automated Hematology Analyser, XR-1000
- XQ-Series Automated Hematology Analyser, model XQ-320

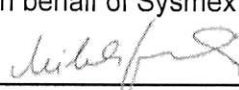
are to be used according to the instructions for use provided by Sysmex and with Sysmex Reagents, Sysmex Controls and Sysmex Calibrators.

The Reagents, Controls and Calibrators listed on the following pages (2-5) are allowed to be used on Sysmex Haematology Analysers.

On behalf of Sysmex Europe SE

Date: 22.12.2023

Place: 22848 Norderstedt, Germany

  
i.A. Nenad Milutinovic  
Director Regulatory Affairs  
Registration Support



Sysmex Europe SE  
Bornbarch 1  
22848 Norderstedt

### Automated Hematology Analyser XN-L series (XN-330, XN-530)

| REF no.  | Product Name                      |
|----------|-----------------------------------|
| CU228496 | CELLPACK DCL 10L                  |
| CT661628 | CELLPACK DCL 20 L (optional)      |
| BG689680 | LYSERCELL WDF 2L (optional)       |
| AZ124801 | LYSERCELL WDF 2L                  |
| 90411414 | SULFOLYSER 5L (optional)          |
| 90411317 | SULFOLYSER 3x500mL (optional)     |
| 05433514 | SULFOLYSER 1x500mL                |
| AA325279 | FLUOROCCELL WDF 2x22mL (optional) |
| BJ284784 | FLUOROCCELL WDF 2x22mL            |
| BQ095093 | CELLCLEAN AUTO 20x4mL             |
| 83401621 | CELLCLEAN 50mL                    |
| BC553492 | XN CAL                            |
| CC211992 | XN-L CHECK                        |
| BS660546 | XN-L CHECK                        |
| AE908164 | XN-L CHECK                        |

### Automated Hematology Analyser XN-L series (XN-350, XN-550)

| REF no.  | Product Name                      |
|----------|-----------------------------------|
| CU228496 | CELLPACK DCL 10L                  |
| CT661628 | CELLPACK DCL 20 L (optional)      |
| AR829995 | CELLPACK DFL 1L                   |
| BT965910 | CELLPACK DFL 2x1,5L (optional)    |
| BG689680 | LYSERCELL WDF 2L                  |
| AW993605 | LYSERCELL WDF 2x4L (optional)     |
| AL337564 | LYSERCELL WDF 5L (optional)       |
| 90411414 | SULFOLYSER 5L (optional)          |
| 90411317 | SULFOLYSER 3x500mL                |
| 05433514 | SULFOLYSER 1x500mL                |
| CU920210 | FLUOROCCELL RET 2x12mL            |
| BN337547 | FLUOROCCELL RET 2x12mL (optional) |
| AA325279 | FLUOROCCELL WDF 2x22mL            |
| CV377552 | FLUOROCCELL WDF 2x42mL (optional) |
| BQ095093 | CELLCLEAN AUTO 20x4mL             |
| 83401621 | CELLCLEAN 50mL                    |
| AL359722 | XN CHECK                          |
| CU248646 | XN CHECK                          |



|          |             |
|----------|-------------|
| AE474952 | XN CHECK    |
| BD007680 | XN CHECK BF |
| BC553492 | XN CAL      |
| CC211992 | XN-L CHECK  |
| BS660546 | XN-L CHECK  |
| AE908164 | XN-L CHECK  |

#### Automated Hematology Analyser XN-series (XN-1000, XN-2000)

| REF no.  | Product Name                  |
|----------|-------------------------------|
| CU228496 | CELLPACK DCL 10L              |
| CT661628 | CELLPACK DCL 20L              |
| BT965910 | CELLPACK DFL 2x1,5L           |
| AR829995 | CELLPACK DFL 1L (optional)    |
| BL121531 | LYSERCELL WNR 5L              |
| AN577063 | LYSERCELL WNR 2x4L            |
| AL337564 | LYSERCELL WDF 5L              |
| BG689680 | LYSERCELL WDF 2L (optional)   |
| AW993605 | LYSERCELL WDF 2x4L            |
| 90411414 | SULFOLYSER 5L                 |
| 90411317 | SULFOLYSER 3x500mL (optional) |
| 05433514 | SULFOLYSER 1x500mL (optional) |
| CY787031 | FLUOROCCELL PLT 2x12mL        |
| CS412800 | LYSERCELL WPC 2x1,5L          |
| AE228898 | FLUOROCCELL WPC 2x12mL        |
| CP066715 | FLUOROCCELL WNR 2x82mL        |
| BN337547 | FLUOROCCELL RET 2x12 mL       |
| CV377552 | FLUOROCCELL WDF 2x42mL        |
| AA325279 | FLUOROCCELL WDF 2x22mL        |
| BQ095093 | CELLCLEAN AUTO 20x4mL         |
| 83401621 | CELLCLEAN 50mL                |
| AL359722 | XN CHECK                      |
| CU248646 | XN CHECK                      |
| AE474952 | XN CHECK                      |
| BD007680 | XN CHECK BF                   |
| BC553492 | XN CAL                        |
| AR511993 | XN CAL PF                     |
| CN464998 | PLATELET CHECK L1             |



**Automated Hematology Analyser XP series, model: XP-300**

| REF no.    | Product Name                 |
|------------|------------------------------|
| 834001110  | CELLPACK 10 L                |
| 83400116   | CELLPACK 20 L                |
| 97405216   | STROMATOLYSER-WH 3x 500 mL   |
| 83401621   | CELLCLEAN 50ML               |
| AK636886   | EIGHTCHECK-3WP L 12 x 1,5 mL |
| AT566446   | EIGHTCHECK-3WP N 12 x 1,5 mL |
| AT965319   | EIGHTCHECK-3WP H 12 x 1,5 mL |
| AH650456   | EIGHTCHECK-3WP L 12 x 4,6 mL |
| BS485898   | EIGHTCHECK-3WP N 12 x 4,6 mL |
| AQ721025   | EIGHTCHECK-3WP H 12 x 4,6 mL |
| 160-4002-0 | SCS-1000                     |

**XQ-Series Automated Hematology Analyser, model: XQ-320**

| REF no.    | Product Name                 |
|------------|------------------------------|
| 834001110  | CELLPACK 10 L                |
| 83400116   | CELLPACK 20 L                |
| 97405216   | STROMATOLYSER-WH 3x 500 mL   |
| 83401621   | CELLCLEAN 50ML               |
| AK636886   | EIGHTCHECK-3WP L 12 x 1,5 mL |
| AT566446   | EIGHTCHECK-3WP N 12 x 1,5 mL |
| AT965319   | EIGHTCHECK-3WP H 12 x 1,5 mL |
| AH650456   | EIGHTCHECK-3WP L 12 x 4,6 mL |
| BS485898   | EIGHTCHECK-3WP N 12 x 4,6 mL |
| AQ721025   | EIGHTCHECK-3WP H 12 x 4,6 mL |
| 160-4002-0 | SCS-1000                     |



# **XR-Series Automated Hematology Analyser, XR-1000**

| REF no.  | Product Name                  |
|----------|-------------------------------|
| CU228496 | CELLPACK DCL 10L              |
| CT661628 | CELLPACK DCL 20L              |
| BT965910 | CELLPACK DFL 2x1,5L           |
| AR829995 | CELLPACK DFL 1L (optional)    |
| BL121531 | LYSERCELL WNR 5L              |
| AN577063 | LYSERCELL WNR 2x4L            |
| AL337564 | LYSERCELL WDF 5L              |
| BG689680 | LYSERCELL WDF 2L (optional)   |
| AW993605 | LYSERCELL WDF 2x4L            |
| 90411414 | SULFOLYSER 5L                 |
| 90411317 | SULFOLYSER 3x500mL (optional) |
| 05433514 | SULFOLYSER 1x500mL (optional) |
| CY787031 | FLUOROCCELL PLT 2x12mL        |
| CS412800 | LYSERCELL WPC 2x1,5L          |
| AE228898 | FLUOROCCELL WPC 2x12mL        |
| CP066715 | FLUOROCCELL WNR 2x82mL        |
| BN337547 | FLUOROCCELL RET 2x12 mL       |
| CV377552 | FLUOROCCELL WDF 2x42mL        |
| AA325279 | FLUOROCCELL WDF 2x22mL        |
| BQ095093 | CELLCLEAN AUTO 20x4mL         |
| AL359722 | XN CHECK                      |
| CU248646 | XN CHECK                      |
| AE474952 | XN CHECK                      |
| BD007680 | XN CHECK BF                   |
| BC553492 | XN CAL                        |
| AR511993 | XN CAL PF                     |



# Certificate

Standard **ISO 9001:2015**

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

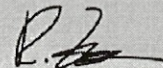
Certificate Holder: **SYSMEX CORPORATION**  
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan  
including the locations according to annex

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



# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1254782-1

Certificate Holder: 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 and gene variants analysis  
set (for cancer genome profiling)  
Product categories: Analyzers and reagents for hematological  
test, blood coagulation test, immune serum test, biochemical  
test, genetic test, bacteriological test and urine test

Installation is not applicable for reagents and gene variants  
analysis set (for cancer genome profiling)

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

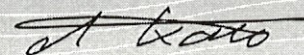
Effective date: 2024-08-01

Expiry date: 2027-07-31

Issue date: 2024-07-04

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

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



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

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## EU Declaration of Conformity

**Product identification:**

|                  |                                                 |
|------------------|-------------------------------------------------|
| Product name:    | CELLPACK                                        |
| Model name:      | N/A                                             |
| REF code:        | 834-0011-6, 834-0011-10, 884-0891-5, 884-0871-1 |
| BUDI-DI:         | 4987562CELLPACKE5                               |
| 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:**

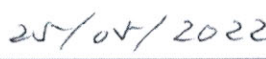
- ☒ A    ☐ B    ☐ C    ☐ D

**Conformity route:**

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

**Common Specification:**

N/A

|                                                                                     |                                                                                     |                                                                                       |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
|  |  |  |
| Takashi Demachi                                                                     | Kobe Japan                                                                          | 25/05/2022                                                                            |
| Executive Vice President                                                            | Place                                                                               | Date<br>(DD.MM.YYYY)                                                                  |
| Name                                                                                | Function                                                                            |                                                                                       |

Sysmex Corporation

1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan  
Tel 81-78-265-0500 Fax 81-78-265-0524



www.sysmex.co.jp

## EU Declaration of Conformity

**Product identification:**

|                  |                          |
|------------------|--------------------------|
| Product name:    | STROMATOLYSER-WH         |
| Model name:      | N/A                      |
| REF code:        | 974-0521-6               |
| BUDI-DI:         | 4987562STROMATOLYSERWHPH |
| 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:**

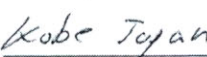
☒ A    ☐ B    ☐ C    ☐ D

**Conformity route:**

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

**Common Specification:**

N/A

|                                                                                     |                                                                                     |              |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------|
|  |  | 25/05/2022   |
| Takashi Demachi                                                                     | Name                                                                                | Date         |
| Executive Vice President                                                            | Function                                                                            | (DD.MM.YYYY) |

Sysmex Corporation

1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan  
Tel 81-78-265-0500 Fax 81-78-265-0524



www.sysmex.co.jp

## 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:**

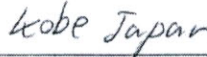
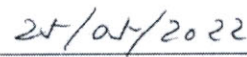
- ☒ A    ☐ B    ☐ C    ☐ D

**Conformity route:**

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

**Common Specification:**

N/A

|                                                                                     |                                                                                     |                                                                                       |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
|  |  |  |
| Takashi Demachi                                                                     | Kobe Japan                                                                          | 25/05/2022                                                                            |
| Executive Vice President                                                            | Place                                                                               | Date<br>(DD.MM.YYYY)                                                                  |
| Name                                                                                | Function                                                                            |                                                                                       |

Sysmex Corporation



# 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: EIGHTCHECK-3WP

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.

