



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  
Alan 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







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

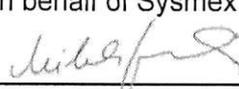
are to be used according to the instructions for use provided by Sysmex and with Sysmex Reagents, Sysmex Controls and Sysmex Calibrators.

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**  
Sysmex Europe SE  
Bornbarch 1  
22848 Norderstedt

10/2023



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 Bayerel (CEO)  
Yuki Hyogu  
Stefanie Schaal  
Matthias Voelkel

COMMERZBANK AG  
Hamburg  
IBAN DE20 0004 0000 0287 1879 00  
SWIFT/BIC COBADEFFXXX

www.sysmex-europe.com



**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	FLUROCELL WDF 2x22mL (optional)
BJ284784	FLUROCELL 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	FLUROCELL RET 2x12mL
BN337547	FLUROCELL RET 2x12mL (optional)
AA325279	FLUROCELL WDF 2x22mL
CV377552	FLUROCELL 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	FLUROCELL PLT 2x12mL
CS412800	LYSERCELL WPC 2x1,5L
AE228898	FLUROCELL WPC 2x12mL
CP066715	FLUROCELL WNR 2x82mL
BN337547	FLUROCELL RET 2x12 mL
CV377552	FLUROCELL WDF 2x42mL
AA325279	FLUROCELL 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	FLUROCELL PLT 2x12mL
CS412800	LYSERCELL WPC 2x1,5L
AE228898	FLUROCELL WPC 2x12mL
CP066715	FLUROCELL WNR 2x82mL
BN337547	FLUROCELL RET 2x12 mL
CV377552	FLUROCELL WDF 2x42mL
AA325279	FLUROCELL 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**

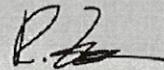
Certificate Holder: **SYSMEX CORPORATION**  
1-5-1 Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan  
including the locations according to annex

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.

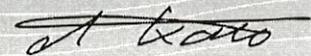
Report No.: 150287325-301

Effective date: 2024-08-01

Expiry date: 2027-07-31

Issue date: 2024-07-04

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



Atsushi Kato

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

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



## EU Declaration of Conformity

Product identification:

Product name: CELLPACK DCL  
 Model name: N/A  
 REF code: CT-661-628, CU-228-496  
 BUDI-DI: 4987562CELLPACKDCLX9  
 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

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



## EU Declaration of Conformity

Product identification:

Product name:	SULFOLYSER
Model name:	N/A
REF code:	054-3351-4, 904-1131-7, AS788212, 904-1141-4
BUDI-DI:	4987562SULFOLYSERBV
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:

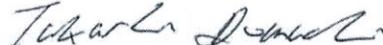
- A     B     C     D

Conformity route:

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

Common Specification:

N/A

	<i>Kobe Japan</i>	<i>25/05/2022</i>
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: Lysercell WDF  
 Model name: N/A  
 REF code: AL-337-564, BG-689-680, AZ-124-801, AW-993-605  
 BUDI-DI: 4987562LysercellWDFXJ  
 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

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

Sysmex Corporation



## EU Declaration of Conformity

Product identification:

Product name: Fluorocell WDF  
 Model name: N/A  
 REF code: AE687941, BY458697, BJ284784, CV-377-552, AA-325-279  
 BUDI-DI: 4987562FLUOROCELLWDFWE  
 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:

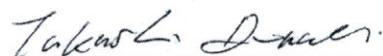
- A     B     C     D

Conformity route:

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

Common Specification:

N/A

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



## 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

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

System 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: XN-L CHECK

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.

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## 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.

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## Product identification:

Product name: XN CAL

Classification: Other device (except Annex II and self-testing devices)

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## List of Applied Standards:

- Harmonised Standards used for conformity assessment are listed in the technical documentation.

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## Legal Manufacturer:

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan

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

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## Authorised representative:

Name: SYSMEX EUROPE SE

Address: Bornbarch 1, 22848 Norderstedt, Germany

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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.

