



Sysmex Europe SE · Deelbøge 19 D · 22297 Hamburg · Germany

To whom it may concern

Sysmex Europe SE
Deelbøge 19 D
22297 Hamburg, Germany
Phone +49 40 527 26-0
Fax +49 40 527 26-100
info@sysmex-europe.com

LETTER OF AUTHORIZATION

Whereas Sysmex Europe SE, who are established, reputable and authorised representative in Europe, Middle East and Africa (EMEA region), officially announced by the manufacturer Sysmex Corporation, having its principal place of business at 4-4-4 Takatsukadai, Nishi-ku, Kobe 651- 2271, Japan, and having the power to grant authorizations to local representatives within the above mentioned markets, do hereby declare that the company

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.

08/2005



Company registered at
District Court Hamburg under
HRB 193509
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
Dr Sanjeev Kumar
Stefanie Schaal
Matthias Völkel

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

www.sysmex-europe.com





This declaration is valid until 31 March 2027 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 2, 2026

Place: 22297 Hamburg, Germany



Matthias Voelkel
Senior Executive Officer
Member of Management Board



Sysmex Europe SE
Deelbøge 19 D
22297 Hamburg

Certificate

Standard **ISO 9001:2015**

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

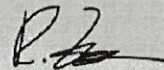
Certificate Holder: **SYSMEX CORPORATION**
1-5-1 Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
including the locations according to annex

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

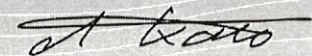
Scope: Design and development, manufacture, distribution,
installation and service of blood analyzer, urine analyzer,
related reagents and accessories and gene variants analysis
set (for cancer genome profiling)
Product categories: Analyzers and reagents for hematological
test, blood coagulation test, 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>

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EC Declaration of Conformity

Application of Council Directive:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices,
- 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment and its related amending directives including the (EU) 2015/863 amending Annex II of the Directive 2011/65/EU,
- 2014/53/EU of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment.

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,
- Directive 2011/65/EU based on the conformity assessment procedure in accordance with EN IEC 63000: 2018,
- Directive 2014/53/EU based on the conformity assessment procedures using harmonized standards EN 50364:2010, EN 61010-2-101:2002, EN 61326-2-6:2006, EN 301 489-1 V2.2.0, EN 301 489-3 V2.1.1 and EN 300 330 V2.1.1 in accordance with Annex II Conformity Assessment Module A

Product identification:

Product name: Automated Hematology Analyzer XN series
System Name: XN-1000, XN-1500, XN-2000, XN-3000, XN-3100, XN-9000, XN-9100, XN-9200
Model name: XN-10, XN-20
Accessories: SA-01*, SA-10*, SA-20*, SA-21*, SA-30*, SA-31*, BT-40*, CV-50*, CV-55*, CV-60*, CV-65*, CV-70*, ST-40*, ST-41*, ST-42*, TU-40*, RR-10*
Classification: Other device (except Annex II and self-testing devices)

*Conformity to 2014/53/EU does not apply

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: Sep. 15, 2021
Takashi Demachi, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE GMBH
Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: [Signature] Date: 29/09/2021
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 25.05.2022 or until a revised declaration is Issued due to product modifications.



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)

Sysmex Corporation



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:

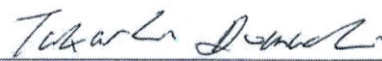
- A B C D

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 WNR
Model name:	N/A
REF code:	BL-121-531, AN-577-063
BUDI-DI:	4987562LysercellWNRZ8
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:


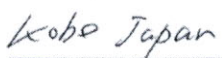
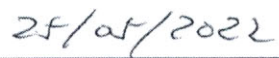
- A B C D

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
Function		(DD.MM.YYYY)

System 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 WNR
Model name:	N/A
REF code:	BG128712, CP-066-715
BUDI-DI:	4987562FLUOROCELLWNR4
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	Name	Date
Executive Vice President	Function	(DD.MM.YYYY)



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:

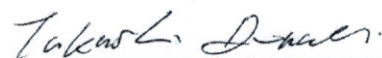
- A B C D

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:	CELLPACK DFL
Model name:	N/A
REF code:	BT-965-910, AR-829-995
BUDI-DI:	4987562CELLPACKDFLXJ
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)

System Corporation



EU Declaration of Conformity

Product identification:

Product name: Fluorocell RET
 Model name: N/A
 REF code: CB702452, BR416395, BN-337-547, CU-920-210
 BUDI-DI: 4987562FLUOROCELLRETWL
 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)

Sysmex Corporation



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:

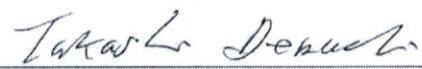
- A B C D

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 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: Bombarch 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: XN CAL

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.



Certificate

Herewith we confirm

Serghei Costov

from ECHIPAMED PLUS, Moldova

the successful completion of the

XN Technical Training

from October 17, 2013 - October 25, 2013
in Norderstedt, Germany

Theoretical knowledge, complemented with practical exercises,
was given on the following subjects:

Installation of analyser and software

Operation and service procedures

Mechanical adjustment

Calibration and sensitivity adjustment

Maintenance

Troubleshooting



October 25, 2013



Sysmex Europe GmbH

Sysmex
Academy