



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  
Dr. Sanjeev Kumar  
Stefanie Schaal  
Matthias Voelkel

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

[www.sysmex-europe.com](http://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 2026 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 17, 2025

Place: 22848 Norderstedt, Germany

  
Matthias Voelkel  
Senior Executive Officer  
Member of Management Board



Sysmex Europe SE  
Bornbarch 1  
22848 Norderstedt





# Certificate

Standard **ISO 9001:2015**

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

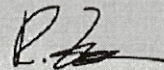
Certificate Holder: **SYSMEX CORPORATION**  
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan  
including the locations according to annex

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



**TÜVRheinland®**  
Precisely Right.



# 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

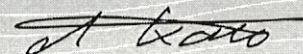
Effective date: 2024-08-01

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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# 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: Sinem Yaman 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:

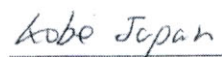
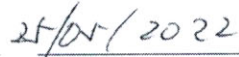
- ☒ A    ☐ B    ☐ C    ☐ D

Conformity route:

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

Common Specification:

N/A

|   |   |   |
|---|---|---|
|  |  |  |
| Takashi Demachi   | Kobe Japan  | 25/05/2022  |
| Executive Vice President  | Place   | Date<br>(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



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## 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 |

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- ☒ 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  | Place   |
| Executive Vice President  | Function  | Date<br>(DD.MM.YYYY)  |

Sysmex Corporation

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## 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 |

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- ☒ Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices  
☐ Other Regulation(s)/Directive(s) as applicable for the device(s):

**Risk class:**


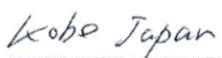
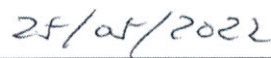
- ☒ A    ☐ B    ☐ C    ☐ D

**Conformity route:**

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

**Common Specification:**

N/A

|   |   |   |
|---|---|---|
|  |  |  |
| Takashi Demachi   | Name  | Place   |
| Executive Vice President  | Function  | Date<br>(DD.MM.YYYY)  |

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## 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 |

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- ☒ 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  | Name  | Date  |
|   | 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



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## 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:**

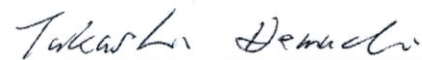
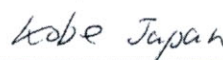

- ☒ A    ☐ B    ☐ C    ☐ D

**Conformity route:**

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

**Common Specification:**

N/A

|   |  |   |
|---|--|---|
|  |  |  |
| Takashi Demachi   | Kobe Japan   | 27/05/2022  |
| Executive Vice President  | Name   | Date  |
|   | Function   | (DD.MM.YYYY)  |

Sysmex Corporation

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## 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:         | 4987562FLUOROCCELLWDFWE                              |
| 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:**

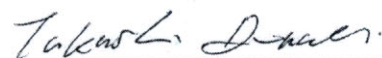

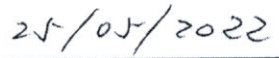
- ☒ A    ☐ B    ☐ C    ☐ D

**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

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Tel 81-78-265-0500 Fax 81-78-265-0524



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## 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

*Takashi Demachi*

Takashi Demachi  
Executive Vice President

Name  
Function

*Kobe Japan*

Place

*25/05/2022*

Date  
(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



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## 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 |

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- ☒ Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices  
☐ Other Regulation(s)/Directive(s) as applicable for the device(s):

**Risk class:**

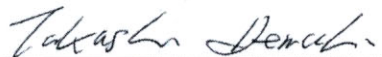
- ☒ A    ☐ B    ☐ C    ☐ D

**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) |

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 |

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- ☒ Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices  
☐ Other Regulation(s)/Directive(s) as applicable for the device(s):

**Risk class:**

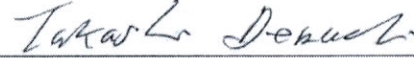
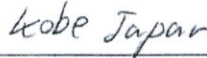
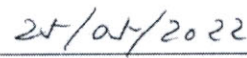
- ☒ A    ☐ B    ☐ C    ☐ D

**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



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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.

## 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: 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.



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