



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





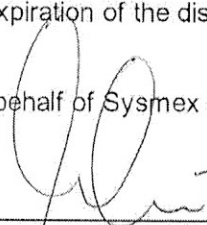
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

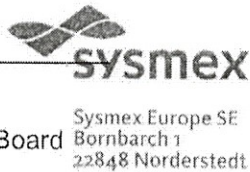
This declaration is valid until 31 March 2025 and may be revoked unilaterally by Sysmex in writing before that date for due cause. Such due cause shall, among others, be the termination or expiration of the distributorship relationship, if any, between Sysmex and the **COMPANY**.

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

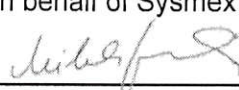
are to be used according to the instructions for use provided by Sysmex and with Sysmex Reagents, Sysmex Controls and Sysmex Calibrators.

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**

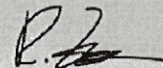
Certificate Holder: **SYSMEX CORPORATION**
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
including the locations according to annex

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

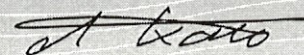
Effective date: 2024-08-01

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 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:

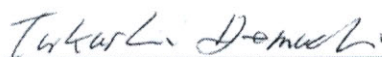
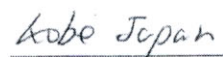
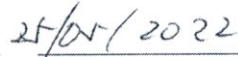
- ☒ A ☐ B ☐ C ☐ D

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 (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:	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:

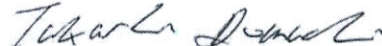
- ☒ A ☐ B ☐ C ☐ D

Conformity route:

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

Common Specification:

N/A

		
Takashi Demachi	Name	Place
Executive Vice President	Function	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



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:

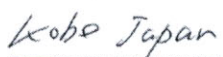
- ☒ A ☐ B ☐ C ☐ D

Conformity route:

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

Common Specification:

N/A

		
Takashi Demachi	Name	Place
Executive Vice President	Function	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



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

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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



www.sysmex.co.jp

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

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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:

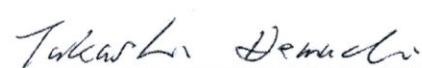
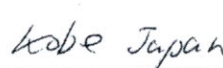
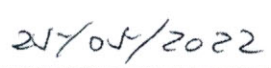
- ☒ A ☐ B ☐ C ☐ D

Conformity route:

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

Common Specification:

N/A

		
Takashi Demachi	Kobe Japan	27/05/2022
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



www.sysmex.co.jp

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:

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Single Registration Number:	DE-AR-000022333
Address:	Bornbarch 1, 22848 Norderstedt, Germany

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

Risk class:

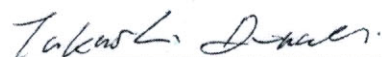
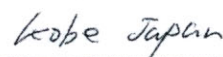
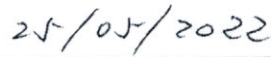
- ☒ A ☐ B ☐ C ☐ D

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 (DD.MM.YYYY)
Name	Function	

Sysmex Corporation

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



www.sysmex.co.jp

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:

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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



www.sysmex.co.jp

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:

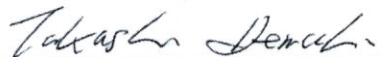
- ☒ A ☐ B ☐ C ☐ D

Conformity route:

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

Common Specification:

N/A

	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:	Fluorocell PLT
Model name:	N/A
REF code:	CY787031
BUDI-DI:	4987562FLUOROCCELLPLTWX
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:

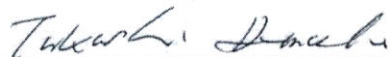
- ☒ A ☐ B ☐ C ☐ D

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)

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:

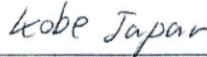
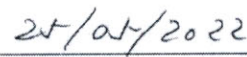
- ☒ A ☐ B ☐ C ☐ D

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 (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

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.



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.



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 PF

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.



CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

DICHIARAZIONE DI CONFORMITA' CE
CE DECLARATION OF CONFORMITY
DECLARAÇÃO CE CONFORMIDADE

Aptaca S.p.A.

SRN (Numero di Registrazione Unico): IT-MF-000010416
SRN (Single Registration Number):

DICHIARA / DECLARES / DECLARA

Che il dispositivo medico diagnostico in vitro di seguito descritto:

That in vitro diagnostic medical devices described as follows:

Que os dispositivos medicos de diagnóstico in vitro a seguir discriminados como:

PROVETTE PER ANALISI CON VUOTO PRECALIBRATO
VACUUM TEST TUBES - TUBOS DE EXAME VACUO



DISPOSITIVI STERILI - STERILE DEVICES - DISPOSITIVOS ESTEREIS

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)
(cujas referencias estão descritos no anexo 1)

BASIC UDI-DI (Global Model Number - GMN):

- Provette sottovuoto per sangue / Blood vacuum test tubes: 805577609FT15BLOODVAC01LU
- Provette sottovuoto per urina / Urine vacuum test tube: 805577609FT15URINEVAC026U
- Kit urine / Urine kit: 805577609FT15KITURINE035L

> Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000 e s.m.i.

Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.

São fabricados de acordo com os requisitos essenciais da Directiva 98/79/CE anexo I, datada de 27 Outubro 1998 posta em vigor pelo Decreto 332 datado de 08/09/2000

> I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.

The devices as per Annex 1 do not do not fall under list A or B of annex II of the Directive 98/79/EC.

Os dispositivos mencionados no anexo I não se enquadram na lista A e/ou B da Directiva 98/79/CE

> La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.

The present Declaration was drafted in accordance with annex III (with the exception of point 6) to Directive 98/79/EC.

A presente Declaração está redigida de acordo com o anexo III (com exceção do ponto 6) da Directiva 98/79/CE

Rilasciato / Released
Canelli, 20.05.2022

Provette per analisi con vuoto precalibrato - Prodotti sterili
Vacuum collection test tubes - Sterile products

Duilio BUONO

Quality Assurance Manager

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

Anexo 1 da Declaração de Conformidade 98/79/CE

Cod.	DESCRIZIONE	DESCRIPTION
30001	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, without additive, white cap, interior sterile.
30002	Provette sottovuoto 3,0 ml, in PET Ø13x75 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 3.0 ml, in PET, Ø13x75 mm, without additive, white cap, interior sterile.
30003	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, without additive, white cap, interior sterile.
30004	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, senza additivo, tappo bianco, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, without additive, white cap, interior sterile.
30020	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with clot activator, red cap, interior sterile.
30021	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with clot activator, red cap, interior sterile.
30022	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, with clot activator, red cap, interior sterile.
30023	Provette sottovuoto 9,0 ml, in PET Ø16x100 mm, con acceleratore, tappo rosso, sterile interno.	Vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with clot activator, red cap, interior sterile.
30011	Provette sottovuoto 3,5 ml, in PET Ø13x75 mm, con acceleratore + gel, tappo rosso, sterile interno.	Vacuum test tubes 3.5 ml, in PET, Ø13x75 mm, with clot activator + gel, red cap, interior sterile.
30012	Provette sottovuoto 5,0 ml, in PET Ø13x100 mm, con acceleratore + gel, tappo rosso, sterile interno.	Vacuum test tubes 5.0 ml, in PET, Ø13x100 mm, with clot activator + gel, red cap, interior sterile.
30013	Provette sottovuoto 8,0 ml, in PET Ø16x100 mm, con acceleratore + gel, tappo rosso, sterile interno.	Vacuum test tubes 8.0 ml, in PET, Ø16x100 mm, with clot activator + gel, red cap, interior sterile.
30014	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con acceleratore + rapid gel, tappo rosso, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with clot activator + rapid gel, red cap, interior sterile.
30031	Provette sottovuoto 3,5 ml, in PET Ø13x75 mm, con acceleratore + gel, tappo gold, sterile interno.	Vacuum test tubes 3.5 ml, in PET, Ø13x75 mm, with clot activator + gel, gold cap, interior sterile.
30032	Provette sottovuoto 5,0 ml, in PET Ø13x100 mm, con acceleratore + gel, tappo gold, sterile interno.	Vacuum test tubes 5.0 ml, in PET, Ø13x100 mm, with clot activator + gel, gold cap, interior sterile.
30033	Provette sottovuoto 8,0 ml, in PET Ø16x100 mm, con acceleratore + gel, tappo gold, sterile interno.	Vacuum test tubes 8.0 ml, in PET, Ø16x100 mm, with clot activator + gel, gold cap, interior sterile.
30200	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30200/1	Provette sottovuoto 1,0 ml, in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 1.0 ml, in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30201	Provette sottovuoto 3,0 ml, in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 3.0 ml, in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30202	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with K3 EDTA, lavender cap, interior sterile.
30203	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, with K3 EDTA, lavender cap, interior sterile.
30204	Provette sottovuoto 9,0 ml, in PET Ø16x100 mm, con K3 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with K3 EDTA, lavender cap, interior sterile.
30100	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with K2 EDTA, lavender cap, interior sterile.
30101	Provette sottovuoto 3,0 ml, in PET Ø13x75 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 3.0 ml, in PET, Ø13x75 mm, with K2 EDTA, lavender cap, interior sterile.
30102	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with K2 EDTA, lavender cap, interior sterile.
30103	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, with K2 EDTA, lavender cap, interior sterile.
30104	Provette sottovuoto 9,0 ml, in PET Ø16x100 mm, con K2 EDTA, tappo lavanda, sterile interno.	Vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with K2 EDTA, lavender cap, interior sterile.
30300	Provette sottovuoto 1,6 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8% per VES, tappo nero, sterile interno.	Vacuum test tubes 1.6 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,2% for ESR, black cap, interior sterile.
30500	Provette sottovuoto 2,7 ml, in PET Ø13x75 mm, con Sodio Citrato 3,2%, tappo azzurro, sterile interno.	Vacuum test tubes 2.7 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,2%, light blue cap, interior sterile.
30501	Provette sottovuoto 3,6 ml, in PET Ø13x75 mm, con Sodio Citrato 3,2%, tappo azzurro, sterile interno.	Vacuum test tubes 3.6 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,2%, light blue cap, interior sterile.
30500/38	Provette sottovuoto 2,7 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8%, tappo azzurro, sterile interno.	Vacuum test tubes 2.7 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,8%, light blue cap, interior sterile.
30501/38	Provette sottovuoto 3,6 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8%, tappo azzurro, sterile interno.	Vacuum test tubes 3.6 ml, in PET, Ø13x75 mm, with Sodium Citrate 3,8%, light blue cap, interior sterile.

Provette per analisi con vuoto precalibrato – Prodotti sterili

Vacuum collection test tubes – Sterile products

20.05.2022



ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

Anexo 1 da Declaração de Conformidade 98/79/CE

COD.	DESCRIZIONE	DESCRIPTION
30503	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Sodio Citrato 3,2%, tappo azzurro, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Sodium Citrate 3.2%, light blue cap, interior sterile.
30503/38	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Sodio Citrato 3,8%, tappo azzurro, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Sodium Citrate 3.8%, light blue cap, interior sterile.
30600	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Sodio Fluoruro + Sodio Eparina per glucosio, tappo grigio, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Sodium Fluoride + Sodium Heparin, gray cap, interior sterile.
30601	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con Sodio Fluoruro + Sodio Eparina per glucosio, tappo grigio, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with Sodium Fluoride + Sodium Heparin, gray cap, interior sterile.
30800	Provette sottovuoto 2,0 ml, in PET Ø13x75 mm, con Litio Eparina, tappo verde, sterile interno.	Vacuum test tubes 2.0 ml, in PET, Ø13x75 mm, with Lithium Heparin, green cap, interior sterile.
30801	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con Litio Eparina, tappo verde, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with Lithium Heparin, green cap, interior sterile.
30802	Provette sottovuoto 6,0 ml, in PET Ø13x100 mm, con Litio Eparina, tappo verde, sterile interno.	Vacuum test tubes 6.0 ml, in PET, Ø13x100 mm, with Lithium Heparin, green cap, interior sterile.
30900	Provette sottovuoto 4,0 ml, in PET Ø13x75 mm, con Litio Eparina + Gel, tappo verde chiaro, sterile interno.	Vacuum test tubes 4.0 ml, in PET, Ø13x75 mm, with Lithium Heparin + Gel, light green cap, interior sterile.
30901	Provette sottovuoto 5,0 ml, in PET Ø13x100 mm, con Litio Eparina + Gel, tappo verde chiaro, sterile interno.	Vacuum test tubes 5.0 ml, in PET, Ø13x100 mm, with Lithium Heparin + Gel, light green cap, interior sterile.
35100	Provette coniche sottovuoto 9,0 ml, in PET, Ø16x100 mm, senza additivo, tappo giallo, sterile interno.	Conical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, without additive, yellow cap, interior sterile.
35150	Provette cilindriche sottovuoto 9,0 ml, in PET, Ø16x100 mm, senza additivo, tappo giallo, sterile interno.	Cylindrical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, without additive, yellow cap, interior sterile.
5060TS+35150	Contenitore urina sottovuoto 60ml + provetta urina sottovuoto 9 ml, blister singolo sterile.	60 ml urine container with vacuum cap + vacuum 9 ml test tube.
5080/SG	Contenitore urina sottovuoto 60ml + provetta urina sottovuoto 9 ml, blister singolo sterile.	60 ml urine container with vacuum cap + vacuum 9 ml test tube.
5081/SG	Contenitore urina sottovuoto 60ml + provetta urina sottovuoto 9 ml con additivo, blister singolo sterile.	60 ml urine container with vacuum cap + vacuum 9 ml test tube with additive.
35150/TB	Provette cilindriche sottovuoto 9,0 ml, in PET, Ø16x100 mm, senza additivo, tappo bianco, sterile interno.	Cylindrical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, without additive, white cap, interior sterile.
35200	Provette coniche sottovuoto 9,0 ml, in PET, Ø16x100 mm, con preservante Acido Borico, tappo giallo, sterile interno.	Conical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with Boric Acid, yellow cap, interior sterile.
35250	Provette cilindriche sottovuoto 9,0 ml, in PET, Ø16x100 mm, con preservante Acido Borico, tappo giallo, sterile interno.	Cylindrical vacuum test tubes 9.0 ml, in PET, Ø16x100 mm, with Boric Acid, yellow cap, interior sterile.
36005	Provette sottovuoto 5,0 ml, in PET Ø13x100 mm, con K2 EDTA + Gel, tappo lavanda, sterile interno.	Vacuum test tubes 5.0 ml, in PET, Ø13x100 mm, with K2 EDTA + Gel, lavender cap, interior sterile.
30400	Provette sterili sottovuoto in PET per VES Ø 9 x 120 mm	Sterile vacuum tubes in PET for VES Ø 9 x 120 mm

