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

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

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

i.A. Nenad Milutinovic
Director Regulatory Affairs
Registration Support

Date: 22.12.2023
Place: 22848 Norderstedt, Germany

Sysmex Europe SE
Bornbarch 1
22848 Norderstedt

Company Location Norderstedt
Registered AG Kiel
HRB 24262 KI
VAT-ID DE 118 687 842
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Chairman of the Supervisory Board
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COMMERZBANK AG
Hamburg
IBAN DE20 2004 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	FLUOROCELL WDF 2x22mL (optional)
BJ284784	FLUOROCELL WDF 2x22mL
BQ095093	CELLCLEAN AUTO 20x4mL
83401621	CELLCLEAN 50mL
BC553492	XN CAL
CC211992	XN-L CHECK
BS660546	XN-L CHECK
AE908164	XN-L CHECK

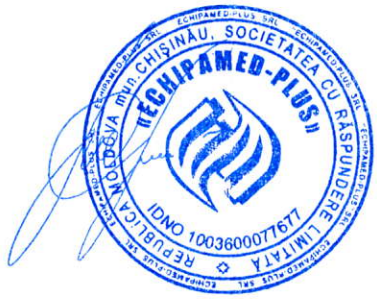
Automated Hematology Analyser XN-L series (XN-350, XN-550)

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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

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

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

Company Version: n/a
Version Approval Date: 05-Jul-2024

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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	25/04/2022
Takashi Demachi Executive Vice President	Name Function	Place	Date (DD.MM.YYYY)

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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

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	25/04/2022
Takashi Demachi Executive Vice President	Name Function	Place	Date (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

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
Takashi Demachi Executive Vice President	Name Function	Place	Date (DD.MM.YYYY)

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600071674 REPUBLICA MOLDOVA mun. CHIȘINĂU

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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:	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

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

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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	24/Oct/2022
Takashi Demachi Executive Vice President	Name Function	Place	Date (DD.MM.YYYY)

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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-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:

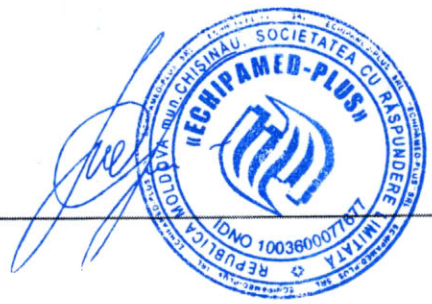
Name: SYSMEX EUROPE SE

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: 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.



sysmex
Lighting the way with diagnostics

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: 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.

CHISINAU, SOCIETATEA CU RASPUNDERE LIMITATA ECHIPAMED-PLUS REPUBLICA MOLDOVA IDNO 1003600077677