Digitally signed by Iurchevici Valeriu
Date: 2023.12.22 16:56:11 EET
Reason: MoldSign Signature
Location: Moldova

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EU Declaration of Conformity

Product identification:

Product name:	CELLPACK
Model name:	N/A
REF code:	834-0011-6, 834-0011-10, 884-0891-5, 884-0871-1
BUDI-DI:	4987562CELLPACKE5
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	Kobe Japan	25/04/2022
Executive Vice President	Function	Place	Date (DD.MM.YYYY)

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EU Declaration of Conformity

Product identification:

Product name:	STROMATOLYSER-WH
Model name:	N/A
REF code:	974-0521-6
BUDI-DI:	4987562STROMATOLYSERWHPH
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
Name	Place	Date (DD.MM.YYYY)
Executive Vice President	Function	

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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: EIGHTCHECK-3WP

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.