Digitally signed by Iurchevici Valeriu
Date: 2023.02.22 20:34:39 EET
Reason: MoldSign Signature
Location: Moldova

sysmex

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:
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 2023 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: 10 June 2022
Place: 22848 Norderstedt, Germany

Sysmex Europe SE
Bornbarch 1
22848 Norderstedt

Matthias Voelkel
Senior Executive Officer

Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt, Germany
Phone +49 40 52726-0
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DECLARATION

As a responsible representative of Sysmex Europe GmbH, I hereby declare that our Sysmex Haematology Analysers

XT-2000i, XT-1800i, XS-1000i, XS-800i, XS-500i, pocH-100i, KX-21N and XP-300

are 'closed systems' and only to be used together with Sysmex Reagents, Sysmex Controls and Sysmex Calibrators. Every change of this closed system by the user is regarded as 'non-specified use' by Sysmex.

The technology of all Sysmex IVD analysers is fine-tuned together with the corresponding reagents used on each single analyser. Thereby, using Sysmex reagents maintains optimum performance as well as optimal and enhanced accuracy of the system. There is a high interdependency between research and using/finding optimal reagents for any new parameter(s). As Sysmex is actively doing research, it is thereby ensured that Sysmex reagents fulfil best practice requirements for any research parameter(s), which later will become diagnostic parameter(s) after the legally required procedures under Annex VIII-IVD-Directive 98/79/EC.

Therefore Sysmex Reagents offer best performance on Sysmex Analysers.

The following Reagents, Controls and Calibrators are allowed to be used on Sysmex Haematology Analysers:

XT-2000i	**XT-1800i**	**pocH-100i**	**XS-1000i**
CELLPACK™	CELLPACK™	pocH-pack 65	CELLPACK™
STROMATOLYSER™-FB	STROMATOLYSER™-FB	pocH-pack 65XL	STROMATOLYSER™-4DS
STROMATOLYSER™-4DS	STROMATOLYSER™-4DS		STROMATOLYSER™-4DL
STROMATOLYSER™-4DL	STROMATOLYSER™-4DL		SULFOLYSER™
SULFOLYSER™	SULFOLYSER™		CELLCLEAN™
RET-SEARCH™ (II)			e-CHECK™ (XE)
CELLCLEAN™	CELLCLEAN™	CELLCLEAN™	e-CHECK™ (XS)
e-CHECK™ (XE)	e-CHECK™ (XE)	EIGHTCHECK™-3WP	SCS-1000
SCS-1000	SCS-1000		
XS-800i	**XS-500i**	**KX-21N**	**XP-300**
CELLPACK™	CELLPACK™	CELLPACK™	CELLPACK™
STROMATOLYSER™-4DS	STROMATOLYSER™-4DS		
STROMATOLYSER™-4DL	STROMATOLYSER™-4DL	STROMATOLYSER™-WH	STROMATOLYSER™-WH
SULFOLYSER™	SULFOLYSER™		
CELLCLEAN™	CELLCLEAN™	CELLCLEAN™	CELLCLEAN™
e-CHECK™ (XE)	e-CHECK™ (XE)	EIGHTCHECK™-3WP	EIGHTCHECK™-3WP
e-CHECK™ (XS)	e-CHECK™ (XS)		
SCS-1000	SCS-1000	SCS-1000	SCS-1000

With kind regards, on behalf of Sysmex Europe GmbH

Norderstedt, August 30, 2013

i.A. Katharina Paucke
Manager Regulatory Affairs

Sysmex Europe GmbH

Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

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Composition of Sysmex Reagents

The composition of Sysmex Reagents is highly confidential! Therefore only active components and those classified as dangerous must be declared on the package label.
The below listed table gives an overview of those components in Sysmex Reagents:

CELLPACK™	SODIUM CHLORIDE 6.4 G/L (=0.64 %) BORIC ACID 1.0 G/L (=0.10 %) SODIUM TETRABORATE 0.2 G/L (=0.02 %) EDTA-2K 0.2 G/L (=0.02 %)	
CELLCLEAN™	SODIUM HYPOCHLORITE (AVAILABLE CONCENTRATION 5.0 %)	
POCH-PACK 65 AND POCH-PACK 65XL	**DILUENT (BLUE)** • SODIUM CHLORIDE 6.38 G/L • BORIC ACID 1.0 G/L • SODIUM TETRABORATE 0.2 G/L • EDTA-2K 0.2 G/L	**LYSING REAGENT (PURPLE)** • SODIUM CHLORIDE 0.6G/L • ORG. QUART. AMMONIUMSALT, 8.5G/L
STROMATOLYSER™-FB	NON-IONIC SURFACTANT 0.40% ORGANIC QUATERNARY AMMONIUM SALT 0.1%	
STROMATOLYSER™-4DS	POLYMETHINE DYE 0.002% METHANOL 3.00% ETHYLENE GLYCOL 96.90%	
STROMATOLYSER™-4DL	NON-IONIC SURFACTANT 0.18% ORGANIC QUATERNARY AMMONIUM SALT 0.08%	
STROMATOLYSER™-WH	ORGANIC QUATERNARY AMMONIUMSALT 8.5 G/L (=0.85 %) SODIUM CHLORIDE 0.5 G/L (=0.05 %)	
SULFOLYSER™	SODIUM LAURYL SULPHATE 0.17%	
RET-SEARCH™ (II)	DILUENT: TRICINE BUFFER 0.18% DYE: POLYMETHINE DYE 0.03% METHANOL 7.1% IN ETHYLENE GLYCOL 92.8%	
e-CHECK™ (XE)	QUALITY CONTROL MATERIAL, CONTAINS STABILIZED HUMAN AND ANIMAL BLOOD	
e-CHECK™ (XS)	QUALITY CONTROL MATERIAL; CONTAINS STABILIZED HUMAN RED BLOOD CELLS	
EIGHTCHECK™-3WP	QUALITY CONTROL MATERIAL; CONTAINS STABILIZED HUMAN RED BLOOD CELLS	
SCS-1000	QUALITY CONTROL MATERIAL; CONTAINS STABILIZED HUMAN RED BLOOD CELLS	

With kind regards,
on behalf of Sysmex Europe GmbH

Norderstedt, August 30, 2013

i.A. Katharina Paucke
Manager Regulatory Affairs

Sysmex Europe GmbH

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 and laboratory information system, and development, design, production and sales of customized recombinant protein

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-05-13 until 2024-07-31.
First certification 1998

2022-05-13

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

TÜVRheinland®
Precisely Right.

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1254782-1

Organization: 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
Product categories: analyzers and reagents for hematological test, blood coagulation test, immune serum test, biochemical test, genetic test, bacteriological test and urine test

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.: 150258788-301
Effective date: 2022-04-28
Expiry date: 2024-07-31
Issue date: 2022-04-28

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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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	

sysmex
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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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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: 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.