

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 Sysmex Corporation, Japan,

as manufacturer for **Sysmex Coagulation Analyser** with Reagents, Accessories, Software and spare parts and as authorised distributor for **Siemens Coagulation Reagents** in the territory of Moldova (together the "**Products**")

do hereby declare that the company

ECHIPAMED Plus SRL Valea Trandafirilor 24 "B", off. 80 MD-2001 Chisinau, Moldova (the "COMPANY")

is the non-exclusive distributor of the "Products" in the territory of Moldova.

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

Matthias Voelkel

Senior ∉xecutive Officer

sysmex

Sysmex Europe SE Bornbarch 1 22848 Norderstedt

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

Management Board: Alain Bayerel (CEO) Alberto Bonacíni Yuki Hyogu Stefanie Schaal Matthias Völkel





Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

To whom it may concern

Sysmex Europe GmbH Bornbarch 1 22848 Norderstedt, Germany Phone +49 40 52726-0 Fax +49 40 52726-100 info@sysmex-europe.com

#### 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 <sup>IM</sup>	CELLPACK'M	pocH-pack 65	CELLPACK <sup>IM</sup>
STROMATOLYSERTM-FB	STROMATOLYSER <sup>TM</sup> -FB	pocH-pack 65XL	STROMATOLYSER <sup>TM</sup> -
STROMATOLYSER™- 4DS	STROMATOLYSERTM-4DS		STROMATOLYSER <sup>TM</sup> -
STROMATOLYSER™- 4DL	STROMATOLYSERTM-4DL	5.15.75.75.75.65.45.K	SULFOLYSER <sup>IM</sup>
SULFOLYSER <sup>IM</sup>	SULFOLYSER <sup>IM</sup>	<b>创新的产品和产品等的企业</b>	CELLCLEAN'M
RET-SEARCH™ (II)		<b>国际中国的国际中国的国际</b>	e-CHECK <sup>IM</sup> (XE)
CELLCLEAN'M	CELLCLEANIM	CELLCLEANIM	e-CHECK <sup>TM</sup> (XS)
e-CHECK <sup>IM</sup> (XE)	e-CHECK <sup>™</sup> (XE)	EIGHTCHECK M-3WP	SCS-1000
SCS-1000	SCS-1000		and Alberta Control of the Control o
XS-800i	XS-500i	KX-21N	XP-300
CELLPACK <sup>IM</sup>	CELLPACKIM	CELLPACK <sup>IM</sup>	CELLPACK <sup>IM</sup>
STROMATOLYSER <sup>TM</sup> - 4DS	STROMATOLYSER™-4DS		
STROMATOLYSER <sup>IM</sup> - 4DL	STROMATOLYSER 1M-4DL	STROMATOLYSER <sup>IM</sup> -WH	STROMATOLYSER M-WH
SULFOLYSER'M	SULFOLYSER <sup>IM</sup>		
CELLCLEAN M	CELLCLEANIM	CELLCLEANIM	CELLCLEAN <sup>IM</sup>
e-CHECK <sup>™</sup> (XE)	e-CHECK <sup>™</sup> (XE)	EIGHTCHECK <sup>IM</sup> -3WP	EIGHTCHECK <sup>IM</sup> -3WP
e-CHECK <sup>™</sup> (XS)	e-CHECKIM (XS)		A Company of the Comp
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

Sysmex Europe GmbH

**SYSMEX** 

Manager Regulatory Affairs

Company Location Norderstedt Registered AG Kiel HRB 4179 VAT-ID DE 118 687 842 WEEE/ElektroG Reg. Nr. DE 159 56 453

**Managing Directors** Dr. Bernd Balkenhol Kazuya Obe Dr. Michael Schaefer Dr. Jürgen Schulze Kohei Sumitani Matthias Völkel

The Bank of Tokyo-Mitsubishi UFJ, Ltd. Hamburg Bank ID-Code 300 107 00 Account Nr. 03 77 13 IBAN DE03 3001 0700 0000 0377 13 SWIFT/BIC Code BOTKDEDX





Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

To whom it may concern

Sysmex Europe GmbH Bornbarch 1 22848 Norderstedt, Germany Phone +49 40 52726-0 Fax +49 40 52726-100 info@sysmex-europe.com

### **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 (PURPL  • SODIUM CHLORIDE 0.6G/  • ORG. QUART. AMMONIUM  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	A 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 <sup>™</sup> (II)	DILUENT: TRICINE BUFFER ( DYE: POLYMETHINE DY METHANOL 7.1% IN ETHYLENE GLY	E 0.03%	
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

Sysmex Europe GmbH

Company Location Norderstedt Registered AG Kiel HRB 4179 VAT-ID DE 118 687 842 WEEE/ElektroG Reg. Nr. DE 159 56 453 Managing Directors Dr. Bernd Balkenhol Kazuya Obe Dr. Michael Schaefer Dr. Jürgen Schulze Kohel Sumitani Matthias Völkel The Bank of Tokyo-Mitsubishi UFJ, Ltd/ Hamburg Bank ID-Code 300 107 00 Account Nr. 03 77 13

Account Nr. 03 77 13 IBAN DE03 3001 0700 0000 0377 13 SWIFT/BIC Code BOTKDEDX



## 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

MUSICO

TÜV Rheinland Cert GmbH Am Grauen Stein · 51105 Köln





### Certificate



### Quality Management System EN ISO 13485:2016

Registration No.:

SX 1254782-1

Organization:

SYSMEX CORPORATION

1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe

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

TÜVRheinland

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

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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

1/9

# Certificate

Standard

ISO 14001:2015

Certificate Registr. No.

09 104 9374

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 Support of In-vitro Diagnostic Medical Devices, Laboratory Equipment, Reagents and Information Technology Systems for Laboratories and Sales of Customized Recombinant Proteins

Proof has been furnished by means of an audit that the requirements of ISO 14001:2015 are met.

Validity:

The certificate is valid from 2020-04-07 until 2023-04-06. First certification 2000

2020-02-25

The stelle

TÜV Rheinland Cert GmbH Am Grauen Stein · 51105 Köln

JAKES OF MULTICAL PROPERTY OF MULTICAL PROPERTY OF ARRANGE PARTY.

( DAKKS

Deutsche Akkreditierungsstelle D-ZM-16031-01-00 TÜVRheinland® Precisely Right. 10/201 10 17 E.Ad. 8 TÜV, TUEV and TLIV are registered trademarks. Utilisation and application requires prior and



### 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:			
	s the manufacturer of the device, take sole responsibility for and mentioned device meets the provisions of the following Regulation:		
□ Regulation EU 2017/746	on In vitro Diagnostic Medical Devices		
☐ Other Regulation(s)/Dire	ective(s) as applicable for the device(s):		
Risk class:  ☑ A □ B □	, ] C		
Conformity route: Annex I+II+III according to Art	icle 48 (10) of EU 2017/746		
Common Specification: N/A			
Takashi Demachi	Name Place Date		
Executive Vice President	Function (DD.MM.YYYY)		
- A	SOCIETATES CONTRACTOR		

Sysmex Corporation

www.sysmex.co.jp

Page 1 of 2



### 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: Single Registration Number: Address:	SYSMEX CORPORATION  JP-MF-000014037  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			
hereby declare that the above  Regulation EU 2017/746	the manufacturer of the device, take sole mentioned device meets the provisions of on <i>In vitro</i> Diagnostic Medical Devices ctive(s) as applicable for the device(s):			
Risk class:  ☑ A □ B □	, C D			
Conformity route: Annex I+II+III according to Arti	icle 48 (10) of EU 2017/746			
Common Specification: N/A				
Thus In Demice	1. Kobe Toyan	2505/20/20		
Takashi Demachi Executive Vice President	Name Place Function	Date (DD.MM.YYYY)		

Sysmex Corporation

www.sysmex.co.jp

Page 1 of 2



### EU Declaration of Conformity

Product identification:	0511015411			
Product name:	CELLCLEAN			
Model name:	N/A			
REF code:	834-0162-1, BU037001			
BUDI-DI:	4987562CELLCLEANP7			
Intended Purpose	See attachment	<u> </u>		
Manufacturer: Name:	SYSMEX COR	PORATION		
Single Registration Number:	JP-MF-000014037			
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan			
Authorised representative:				
Name:	SYSMEX EURO	OPE SE		
Single Registration Number:	DE-AR-000022333			
Address:	Bornbarch 1, 22848 Norderstedt, Germany			
SYSMEX CORPORATION, as hereby declare that the above   ☐ Regulation EU 2017/746 ☐ Other Regulation(s)/Direction   Risk class: ☐ A ☐ B ☐	e mentioned devices  S on In vitro Diagnostive(s) as application	ce meets the provisions	s of the following Regu	
Conformity route: Annex I+II+III according to Art	ticle 48 (10) of El	J 2017/746		
Common Specification: N/A				
Takashi Demachi	Name	Kobe Japan Place	2x/0x/200	25
Executive Vice President	Function	Flace	(DD.MM.YYYY)	
Sysmex Corporation		I EGIN	SOCIETATEA CO PUNDERRE LA WALL OF THE PUNDER PU	w.sysmex.co.jp

1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

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



## 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, Executive Vice President

### Authorised representative:

Name:

SYSMEX EUROPE SE

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

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 Corporation** 

www.sysmex.co.jp