

Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

To whom it may concern

Sysmex Europe GmbH
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 GmbH ("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 and second second

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**.



Company Location Norderstedt Registered AG Kiel HRB 4179 VAT-ID DE 118 687 842 WEEE/ElektroG Reg. Nr. DE 159 56 453 Managing Directors Alain Baverel Seido Biwa Alberto Bonacini Kensuke lizuka Iwane Matsui Stefanie Schaal Jan Willem Schipper Matthias Vdikel COMMERZBANK AG, Hamburg IBAN DE20 2004 0000 0287 1879 00 SWIFT/BIC Code COBADEFFXXX





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 GmbH

Date: 09 February, 2022

Place: 22848 Norderstedt, Germany

Matthias Voelkel

Senior Executive Officer

sysmex

Sysmex Europe GmbH Bornbarch 1 22848 Norderstedt





Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

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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 ^{IM}	CELLPACK'M	pocH-pack 65	CELLPACK ^{IM}
STROMATOLYSERTM-FB	STROMATOLYSER TM -FB	pocH-pack 65XL	STROMATOLYSER TM -
STROMATOLYSER™- 4DS	STROMATOLYSERTM-4DS		STROMATOLYSER TM -
STROMATOLYSER™- 4DL	STROMATOLYSERTM-4DL	5.15.75.75.75.65.45.K	SULFOLYSER ^{IM}
SULFOLYSER ^{IM}	SULFOLYSER ^{IM}	创新的产品和产品,包含的 自由的。	CELLCLEAN ^{IM}
RET-SEARCH™ (II)		国际中国的国际中国的国际	e-CHECK ^{IM} (XE)
CELLCLEAN'M	CELLCLEANIM	CELLCLEANIM	e-CHECK TM (XS)
e-CHECK ^{IM} (XE)	e-CHECK [™] (XE)	EIGHTCHECK™-3WP	SCS-1000
SCS-1000	SCS-1000		#10 g(2000 - 40 0 40 0 0 0 0 0 0 0 0 0 0 0 0 0
XS-800i	XS-500i	KX-21N	XP-300
CELLPACK'M	CELLPACKIM	CELLPACK ^{IM}	CELLPACK ^{IM}
STROMATOLYSER TM - 4DS	STROMATOLYSER™-4DS		
STROMATOLYSER 1M- 4DL	STROMATOLYSER 1M-4DL	STROMATOLYSER ^{IM} -WH	STROMATOLYSER™-WH
SULFOLYSER ^{IM}	SULFOLYSER ^{IM}		
CELLCLEAN M	CELLCLEAN™	CELLCLEANIM	CELLCLEAN ^{IM}
e-CHECK [™] (XE)	e-CHECK [™] (XE)	EIGHTCHECK ^{IM} -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

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





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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 (1 BORIC ACID 1.0 G/L (1 SODIUM TETRABORATE 0.2 G/L (1 EDTA-2K 0.2 G/L (1 1 1 1 1 1 1 1 1 1	=0.10 %) =0.02 %)
CELLCLEAN™	SODIUM HYPOCHLORITE (AVAILABL	E CONCENTRATION 5.0 %)
POCH-PACK 65 AND POCH-PACK 65XL	• 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	A 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 AMMONIUM SODIUM CHLORIDE	MSALT 8.5 G/L (=0.85 %) 0.5 G/L (=0.05 %)
SULFOLYSER™	SODIUM LAURYL SULPHATE	0.17%
RET-SEARCH [™] (II)	DILUENT: TRICINE BUFFER (DYE: POLYMETHINE DY METHANOL 7.1% IN ETHYLENE GLY	E 0.03%
e-CHECK™ (XE)	QUALITY CONTROL MATERIAL, CONTANIMAL BLOOD	TAINS STABILIZED HUMAN AND
e-CHECK™ (XS)	QUALITY CONTROL MATERIAL; CON-	TAINS STABILIZED HUMAN RED BLOOD
EIGHTCHECK™-3WP	QUALITY CONTROL MATERIAL; CON-	TAINS STABILIZED HUMAN RED BLOOD
SCS-1000	QUALITY CONTROL MATERIAL; CONT	TAINS STABILIZED HUMAN RED BLOOD

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



Application of Directives:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means	of	conf	or	mi	tv:
	01	00111	\mathbf{v}		LY

The following product is in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III of the Directive.

Pr	odu	ct i	de	ntif	fica	ati	on:	

Product name:

CELLPACK

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.

Lega	l M	lanui	facti	rer:
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Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date:

8105 1712 MUSIAM

Fernando Andreu, Chief Operations Officer

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until

25.05.2022 or until a revised declaration is Issued due to product modifications.



1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan Tel. +81-78-265-0500 Fax. +81-78-265-0524



Application of Directives:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means of conformity:

The following product is in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III of the Directive.

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\mathbf{P}^{r}	OU.	LICT	Iden	tifica	tion.
	O G	uol	IUUI	unca	uon.

Product name:

STROMATOLYSER-4DL

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:

Hiroshi Yamane, Executive Vice President

Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: MARCH 21 ST 2018

Fernando Andreu, Chief Operations Officer

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until 25.05.2022 or until a revised declaration is Issued due to product modifications.





Application of Directives:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means of conformity:

The following product is in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III of the Directive.

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	roo	luct	ide	entif	icat	ion:
	100	IUCL	10.10	21 1111	IL CIL	IUH I.

Product name:

STROMATOLYSER-4DS

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.

ı	ogol	Man	ufacti	ror
1	0031	1///2/1	HIIACII	11-631.

Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Yamane, Executive Vice President

Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Børnbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: HURCH ZIST 2018

Fernando Andreu, Chief Operations Officer

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until

25.05.2022 or until a revised declaration is Issued due to product modifications.





Application of Directives:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means of conformity:

The following product is in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III of the Directive.

P	roc	luct	ide	ntifi	catio	n'
	100	luct	IUC	111111	Callo	11.

Product name:

SULFOLYSER

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.

Lega	I N/	lanut	factu	rer

Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Hiroshi Yamane, Executive Vice Preside

Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: MARCH 21st 2018

Fernando Andreu, Chief Operations Officer

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until 25.05.2022 or until a revised declaration is Issued due to product modifications.



Application of Directive	
- 98/19/EC 01 2/ Octob	ber 1998 on In Vitro Diagnostic Medical Devices
Means of conformity: The following product - Directive 98/79/EC b Annex III of the Direct	ased on the conformity assessment procedures in accordance with
Product identification: Product name:	CELLCLEAN
Classification:	Other device (except Annex II and self-testing devices)
List of Applied Standard - Harmonised Standard documentation.	rds: Is used for conformity assessment are listed in the technical
Legal Manufacturer: Name:	SYSMEX CORPORATION
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Authorised officer:	Hiroshi Yamane, Executive Vice President
Authorised representa	tive:
Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	Date: MARCH 7(4 2018 Fernando Andreu, Chief Operations Officer

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until 25.05.2022 or until a revised declaration is Issued due to product modifications.



Application of Directive			
- 98/79/EC 01 27 Octob	per 1998 on In Vitro Diagnostic Medical Devices		*********
Means of conformity: The following product - Directive 98/79/EC b Annex III of the Direct	ased on the conformity assessment procedures in acco	ordance with	
Product identification: Product name:	e-CHECK(XS)		
Classification:	Other device (except Annex II and self-testing device)	es)	
documentation. Legal Manufacturer:	s used for conformity assessment are listed in the tech	nnical	
Name:	SYSMEX CORPORATION	0072 1	
Address: Authorised officer:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651 Hiroshi Yamane, Executive Vice President		
Authorised representati	tive:		
Name:	SYSMEX EUROPE GMBH		
Address:	Bornbarch 1, 22848 Norderstedt, Germany		
Authorised officer:	Date: HARCH Fernando Andrea, Chief Operations Officer	8105 7215	NAME OF THE OWNER, OWNE
This declaration of conformity is	issued under the sole responsibility of the manufacturer and	is valid until	

25.05.2022 or until a revised declaration is Issued due to product modifications.

Sysmex Corporation

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

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