

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





### Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

SYSMEX EUROPE GmbH Bornbarch 1 22848 Norderstedt Deutschland

has established and applies a quality management system for medical devices for the following scope:

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:

2019-05-17

Certificate Registration No.:

SX 60137613 0001

An audit was performed. Report No.: 21245244 005

This Certificate is valid until:

2022-05-16

Certification Body



Date 2019-04-29

TÜV Rheinland LGA Products GmbH Tillystraße 2/90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-val

# Certificate

Standard

ISO 14001:2015

Certificate Registr. No.

01 104 110072

Certificate Holder:

SYSMEX EUROPE GmbH

Bornbarch 1 22848 Norderstedt Germany

Scope:

Sales, marketing and service of in-vitro diagnostic medical devices

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

Validity:

The certificate is valid from 2020-07-25 until 2023-07-24.

First certification 2011

2020-03-19

TÜV Rheinland Cert GmbH Am Grauen Stein · 51105 Köln

land®



DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-16031-01-00







### Application of Directives:

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

Means	of	conf	form	itv.
Modilis	O	COLL		IILY.

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.

1								C .			
1	$\mathbf{\nu}$	ro	а	uc	1 10	P	nti	tic	atı.	on	٠
- 1			•			16			21		

Product name:

CELLPACK DCL

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.

1	To the contract of the contrac	1 B /	A	-	_ 1	
ı	Lega	I\/	lan	IIII	CIL	irer.

Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Phiroshi Yamane, Executive Vice President

Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Børnbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: HARCH ZUT 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.



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.

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.

ı	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 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.

F	Prod	LICT	ide	ntif	icati	on'
Г	100	uci	lue	111111	IUali	OII.

Product name:

Lysercell WNR

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:

Date: 13 March, 2018 Hiroshi Yamane, Executive Vice President

#### Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Børnbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: HARCH ZIST 7018

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. Product identification: Product name: Lysercell WDF 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 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan Address: Hiroshi Yamano, Executive Vice President Authorised officer:

Authorised officer: Date: MARCH 21 ST 2018

Fernando Andreu, Chief Operations Officer

SYSMEX EUROPE ØMBH

Bornbarch 1,22848 Norderstedt, Germany

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.

Authorised representative:

Name:

Address:



Application of Directive	es:
- 98/79/EC of 27 Octob	per 1998 on In Vitro Diagnostic Medical Devices
Means of conformity:  The following product - Directive 98/79/EC ba Annex III of the Direct	ased on the conformity assessment procedures in accordance with
Product identification: Product name: Classification:	Fluorocell WNR  Other device (except Annex II and self-testing devices)
List of Applied Standard - Harmonised Standard documentation.	rds: s used for conformity assessment are listed in the technical
Legal Manufacturer: Name: Address:	SYSMEX CORPORATION  1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Authorised officer:	Hiroshi Yamane, Executive Vice President
Authorised representat	tive:
Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	Fernando Andreu, Chief Operations Officer
This declaration of conformity is 25.05.2022 or until a revised decl	issued under the sole responsibility of the manufacturer and is valid until aration is Issued due to product modifications.



Application	of	<b>Directives</b>
-------------	----	-------------------

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

Means	of	conf	fo	rm	ity	:
-------	----	------	----	----	-----	---

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	rod	uct	ide	enti	fica	tion	•
	100	UOL	IG		1100	LIVII	

Product name:

Fluorocell WDF

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 17 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. Product identification: Product name: CELLPACK DFL 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 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan Address: Date: 13 March, 2018 Hiroshi Yamane, Executive Vice President

Authorised representative:

Authorised officer:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date:

MARCHZII 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 of 27 Octob	es: per 1998 on In Vitro Diagnostic Medical Devices
Means of conformity: The following product - Directive 98/79/EC ba Annex III of the Direct	ased on the conformity assessment procedures in accordance with
Product identification:	Fluorocell RET
Classification:	Other device (except Annex II and self-testing devices)
- Harmonised Standard documentation.	rds: s 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: HARCH ZIST 2018

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.

Fernando Andreu, Chief Operations Officer



Application of Directive - 98/79/EC of 27 Octob	es: 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: Address:	SYSMEX CORPORATION  1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan  Date: 13 March 2018
Authorised officer:	Hiroshi Yamane, Executive Vice President
Authorised representa	
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 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.

ì											
ı	Ρ	ro	וור	Ct	10	en	titi	cat	IO	n'	•

Product name:

XN 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:

Tiroshi Yamane, Executive Vice Presiden

Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: HARCH 211 7018

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.

i	_										
1	$\mathbf{L}$	ro	a	lict	10	an	1111	ca	tio	n	*
1		ıv	u	uu	IU			Ua	uu	/ 1 1	

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:

#### Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: HARCH 21st 7015

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 Council Di 98/79/EC of 27 October 19	rective: 98 on In Vitro Diagnostic Medical Devices
JG/19/120 0127 October 19	50 on in vido Diagnostic Medical Devices
Means of conformity:	
	conformity with Directive 98/79/EC based on the test results in accordance with Article 5 of the Directive.
Dun dough interestificantia	
Product identification:	
Product name: Flue	procell PLT
Manufacturer:	
	SMEX CORPORATION
Address: 1-5-	-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073
Country: Japa	
Authorised representative	
***************************************	SMEX EUROPE GMBH
***************************************	nbarch 1, 22848 Norderstedt
Country: Ger	many
Authorised officer:/	hohi Gum
Koh	nei Sumitani
Position: Pres	sident
Date: /	oni/ 27, 2017
Place: Ger	
This certificate was issue	d under sole responsibility of:
This continuate was local	de direct sole responsibility of
Authorised officer:	1 July 1
Keij	ji Fujimito
Position: Exe	cutive Vice President
Date: Apr	il 8, 2011
Place: Japa	an Acceptance
-	TO A MEDIA

Sysmex Corporation

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



www.sysmex.co.jp

# 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 product is in conformity with Directive 98/79/EC based on the test results using harmonised standards in accordance with Article 5 of the Directive.						
Product identification						
Product name:	· galanara, anglesi					
Manufacturer:						
	SYSMEX CORPORATION					
	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073					
Country:						
Authorised represent	ative.					
	SYSMEX EUROPE GMBH					
	Bornbarch 1, 22848 Norderstedt					
	Germany					
Authorised officer:	Kohei Sumitani					
Position:	President					
Date:	April 27, 2017					
Place:	Germany					
This certificate was is	sued under sole responsibility of:					
Authorised officer:	J. J					
	Keiji Fujimito					
Position:	Executive Vice President					
Date:	April 8, 2011					
Place:	Japan					

Sysmex Corporation

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

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