

### 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	identific	cation:
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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.

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Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Hiroshi Vamana Evacutiva Vice President

#### Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date:

8105 112 MUSIAM

Fernando Andreu, Chief Operations Officer





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	100	uct	luci	THIT	auon.

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 TT 2018

Fernando Andreu, Chief Operations Officer





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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.

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		11/11/21/11	HIACH	11.631.

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:

Børnbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: HARCH 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.





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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.

Legal	N/	lanuf	actu	rer

Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Hiroshi Vamora Evacutive

Date: 3 March, 2016

Hiroshi Yamane, Executive Vice President

#### Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: MARCH 21 T ZOIR

Fernando Andreu, Chief Operations Officer



Application of Directive	<i>35</i> .
	per 1998 on In Vitro Diagnostic Medical Devices
30/13/20 012/ 3000	oct 1990 on in Vitto Biagnostic Medical Bevices
Means of conformity: The following product - Directive 98/79/EC back 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)
- Harmonised Standard documentation.	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 representat	tive:
Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	Date: MARCH 219 2018  Formando Andrey Chief Operations Officer



Application of Directive			
- 98/79/EC of 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)	***************************************
List of Applied Standard - Harmonised Standard documentation.	rds: s used for conformity assessment are listed in the tecl	nnical	
Legal Manufacturer: Name:	SYSMEX CORPORATION		
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651	-0073,	Japan
Authorised officer:	Hiroshi Yamane, Executive Vice President	vd.	2018
Authorised representati	tive:		
Name:	SYSMEX EUROPE GMBH		
Address:	Bornbarch 1, 22848 Norderstedt, Germany		
Authorised officer:	Pernando Andrea, Chief Operations Officer	7215	8105
This declaration of conformity is	issued under the sole responsibility of the manufacturer and	is valid	until

Sysmex Corporation

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

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

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