

Application of Directives:

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

Means	of	conf	ormity:
-------	----	------	---------

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:
---------	-----------	---------

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.

	lenal	N.	lani	fact	IFOR
1		11/		ITACTI	Irar

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:

8105 112 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.





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.

Prod	uct	ide	ntifi	catio	on
1 100	aut	100		OULI	

Product name:

STROMATOLYSER-WH

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 Yamano, Executive Vice President

Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: HARCH 21st Zeds

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.

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



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 2(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 Directiv	
- 98/79/EC of 27 Octo	ber 1998 on In Vitro Diagnostic Medical Devices
Means of conformity:	
The following product - Directive 98/79/EC b Annex III of the Directive	pased on the conformity assessment procedures in accordance with
Product identification: Product name:	EIGHTCHECK-3WP
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
Authoricad vocast-	
Authorised representa	
Name:	SYSMEX EUROPE GMBH
Address:	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.

Fernando Andreu, Chief Operations Officer



Date: HARCH ZITT ZOIP

Authorised officer: