

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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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.

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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.





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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.

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Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Hiroshi Vamora Evacutiv

Date: 3 March 2018

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

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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

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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 representative:

Fernando Andreu, Chief Operations Officer

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.

SYSMEX EUROPE ØMBH

Date: MARCH 21 " 2018

Name:

Address:

Authorised officer:



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 back Annex III of the Direct	ased on the conformity assessment procedures in accordance with
Product identification: Product name:	Fluorocell WNR
Classification:	Other device (except Annex II and self-testing devices)
List of Applied Standard - Harmonised Standard documentation. Legal Manufacturer: Name:	s used for conformity assessment are listed in the technical 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: HARCH 21ST 2018 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	Directives
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- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

Means of conformity	Means	of	con	fo	rm	ity
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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

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Application of Directive	
- 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 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: Authorised officer:	SYSMEX CORPORATION 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan Date: 13 March, 2018 Hiroshi Yamane, Executive Vice President
Authorised representa	tive:
Name:	SYSMEX EUROPE GMBH Paraday Sanday Sanday Cormany
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	Fernando Andreu, Chief Operations Officer

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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

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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:

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SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: HARCH 21st 7015

Fernando Andreu, Chief Operations Officer

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