

## 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:

**UXII SHEATH** 

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:

Sysmex Corporation

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: MARCH 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 Directive	es:	
- 98/79/EC of 27 Octob	er 1998 on In Vitro Diagnostic Medical Devices	
Means of conformity: The following product: - Directive 98/79/EC ba	ased on the conformity assessment procedures in a	accordance with
Product identification: Product name:	UXII PACK-SED	
Classification:	Other device (except Annex II and self-testing d	evices)
Oldsomedion.		
- Harmonised Standard documentation.  Legal Manufacturer:	s used for conformity assessment are listed in the	technical
Name:	SYSMEX CORPORATION	(51,0072,1
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe	651-0073, Japan
Authorised officer:	Hiroshi Yamane, Executive Vice President	March, 2018
Authorised representa	tive:	
Name:	SYSMEX EUROPE GMBH	
Address:	Bornbarch 1, 22848 Norderstedt, Germany	
(	January Company of the Company of th	SCH 211 2018
Authorised officer:	Fernando Andreu, Chief Operations Officer	
	Fernando Andrea, Cinei Operations Officer	0.0

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	er 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:	UXII PACK-BAC  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:	SYSMEX CORPORATION
Address: Authorised officer:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan  Linuxu Jamane Date: 13 March 2-018  Hiroshi Yamane, Executive Vice President
Authorised representa	tive:
Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	Fernando Andreu, Chief Operations Officer
This declaration of conformity i	s issued under the sole responsibility of the manufacturer and is valid until claration is Issued due to product modifications.





Application of Directive	
- 98/79/EC of 27 Octob	er 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:	UX II SEARCH -SED  Other device (except Annex II and self-testing devices)
- 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  24 Januare Date: 3 March, 2018  Hiroshi Yamare, Executive Vice President
Authorised representa	ative:
Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	Fernando Andreu, Chief Operations Officer
This declaration of conformity i	s issued under the sole responsibility of the manufacturer and is valid until claration 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 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	cati	on
•		. ~ ~ .	100		JULI	VIII.

Product name:

UX II SEARCH -BAC

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 ZIST 7018

3 March, 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:

MEDITAPE II 9U

Classification:

Other device (except Annex II and self-testing devices)

### Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: JANUARY 3rd 2018

Fernando Andreu, Chief Operations Officer

### Legal Manufacturer:

Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Hiroshi Yamane, Executive Vice President December 28, 2017



### 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:

UX CLEAN -C

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 Vamene Evecutive Vice President

# Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: MARCIT 2117 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 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 by Annex III of the Direct	ased on the conformity assessment procedures in accordance with
Product identification: Product name:	CA CLEAN I
Classification:	Other device (except Annex II and self-testing devices)
List of Applied Standard - Harmonised Standards 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  Date: 13 March 2018
Authorised representat	ive:
Name:	SYSMEX EUROPE GMBH

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.

Bornbarch 1, 22848 Norderstedt, Germany

Fernando Andreu, Chief Operations Officer



Date: MARCH 21 TOOP

Address:

Authorised officer:



Means of conformity:	per 1998 on In Vitro Diagnostic Medical Devices
The following product	ased on the conformity assessment procedures in accordance with
Product identification: Product name:	UFII CONTROL
Classification:	Other device (except Annex II and self-testing devices)
Legal Manufacturer:	SYSMEX CORPORATION
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Authorised officer:	Hiroshi Yamane, Executive Vice President
Authorised representa	ative:
Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	Fernando Andreu, Chief Operations Officer
This declaration of conformity i	s issued under the sole responsibility of the manufacturer and is valid until claration 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	iden	tifica	tion.
1 TOUGUCE	IUCI	ILIIIUC	יו וטווג

Product name:

**UFII CALIBRATOR** 

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 Vamane Executive Vice President

#### Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch I, 22848 Norderstedt, Germany

Authorised officer:

Date: MARCH ZITT ZOIR

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	r	O	d	uct	id	er	ntif	ica	tic	'n'
		v	v	UOL	10	VI	111	100	LIC	/ 11 1 4

Product name:

MEDITAPE CHECK 1

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	l egal	N/	ani	ifacti	Iror
-1		11/	1711	1121111	116-21

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: MANCOL 21 TO 18

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.

Product	identi	fication:
---------	--------	-----------

Product name:

MEDITAPE CHECK 2

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: HARCH 21" 7019

Fernando Andrew, 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.



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.

D 1 1	. 1	
Product	Identitio	ation
1 TOUGUCE	Idelitille	auon.

Product name:

SG Calibrator

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

March, 2018

#### Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848/Norderstedt, Germany

Authorised officer:

Date: HARCH ZI'T ZOIR

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.

