Công ty TNHH SYSMEX Việt Nam

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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 products are in conformity with
- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III,

Product identification:

Product name:	Fully Automated Urine Particle Analyzer UF-4000
Accessory:	SA-51
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 Date: 13 March, 2018
Hiroshi Yamane, Executive Vice President

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.

EU Declaration of Conformity

Application of Council Directive:

- 2014/53/EU of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Means of conformity:

The following products are in conformity with

- Directive 2014/53/EU based on the conformity assessment procedures in accordance with Annex II Conformity Assessment Module A,

Health and Safety (Art. 3(1)(a)):	EN 50364:2010 EN 61010-2-101:2002
EMC (Art. 3(1)(b)):	EN 61326-2-6:2006 EN 301 489-1 V2.2.0 EN 301 489-3 V2.1.1
Spectrum (Art. 3(2)):	EN 300 330 V2.1.1

- Directive 2011/65/EU by drawing up the required technical documentation and carrying out the internal production control procedure in line with module A of Annex II to decision No 768/2008EC.

Product identification:

Product name: Fully Automated Urine Particle Analyzer UF-4000

Accessory: SA-51*

*Conformity to 2014/53/EU does not apply.

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: _____ Date: 28.09.2017

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 Date: Sep. 14, 2017

Hiroshi Yamane, Executive Vice President

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 products are in conformity with
- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III,

Product identification:

Product name:	Fully Automated Urine Particle Analyzer UF-5000
Accessory:	SA-51
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 Date: 13 March, 2018
Hiroshi Yamane, Executive Vice President

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.

EU Declaration of Conformity

Application of Council Directive:

- 2014/53/EU of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment
- 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Means of conformity:

The following products are in conformity with

- Directive 2014/53/EU based on the conformity assessment procedures in accordance with Annex II Conformity Assessment Module A,

Health and Safety (Art. 3(1)(a)):	EN 50364:2010 EN 61010-2-101:2002
EMC (Art. 3(1)(b)):	EN 61326-2-6:2006 EN 301 489-1 V2.2.0 EN 301 489-3 V2.1.1
Spectrum (Art. 3(2)):	EN 300 330 V2.1.1

- Directive 2011/65/EU by drawing up the required technical documentation and carrying out the internal production control procedure in line with module A of Annex II to decision No 768/2008EC.

Product identification:

Product name: Fully Automated Urine Particle Analyzer UF-5000

Accessory: SA-51*

*Conformity to 2014/53/EU does not apply.

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: _____ Date: 28.09.2017

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 Date: Sep. 14, 2017

Hiroshi Yamane, Executive Vice President

EC Declaration of Conformity

Application of 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 conformity assessment procedures in accordance with Annex III

Product identification:

Product name:	Fully Automated Urine Particle Digital Imaging Device UD-10
Accessories	CV-11
Classification:	Other device (except Annex II and self-testing devices)

Authorised representative:

Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Takeshi Kubota Date: Feb. 16, 2016

Takeshi Kubota, Managing Director

Legal Manufacturer:

Name:	SYSMEX CORPORATION
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan

Authorised officer: Hiroshi Yamane Date: Jan. 6, 2016

Hiroshi Yamane, Executive Vice President

Sysmex Corporation
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www.sysmex.co.jp

EC Declaration of Conformity

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: UF-CELLPACK CR

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

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Takeshi Kubota Date: 16 July, 2015

Takeshi Kubota, Managing Director

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: Hiroshi Yamane Date: 2 July, 2015

Hiroshi Yamane, Executive Vice President

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EC Declaration of Conformity

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: UF-CELLPACK SF

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

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Takeshi Kubota Date: 16. July, 2015

Takeshi Kubota, Managing Director

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: Hiroshi Yamane Date: 2, July, 2015

Hiroshi Yamane, Executive Vice President

Sysmex Corporation
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EC Declaration of Conformity

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: UF-Fluorocell CR

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

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Takeshi Kubota Date: 1st July, 2015

Takeshi Kubota, Managing Director

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: Hiroshi Yamane Date: 2 July, 2015

Hiroshi Yamane, Executive Vice President

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EC Declaration of Conformity

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: UF-Fluorocell SF

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

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Takeshi Kubota Date: 16. July, 2015

Takeshi Kubota, Managing Director

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: Hiroshi Yamane Date: 2 July, 2015

Hiroshi Yamane, Executive Vice President

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EC Declaration of Conformity

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: UF-CELLSHEATH

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

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Takeshi Kubota Date: 16 July, 2015

Takeshi Kubota, Managing Director

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: Hiroshi Yamane Date: 2 July, 2015

Hiroshi Yamane, Executive Vice President

EC Declaration of Conformity

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: UF-CALIBRATOR

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

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Takeshi Kubota Date: Sep 10, 2015

Takeshi Kubota, Managing Director

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: Hiroshi Yamane Date: Sep 8, 2015

Hiroshi Yamane, Executive Vice President

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EC Declaration of Conformity

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: UF-CONTROL

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

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Takeshi Kubota Date: Sep. 10, 2015

Takeshi Kubota, Managing Director

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: Hiroshi Yamane Date: Sep 8, 2015

Hiroshi Yamane, Executive Vice President

Sysmex Corporation
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