

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: 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.

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:

Hiroshi Yamane
Hiroshi Yamane, Executive Vice President

Date: 13 March, 2018

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Fernando Andreu, Chief Operations Officer

Date: MARCH 21ST 2018

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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Means of conformity:

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Product identification:

Product name: STROMATOLYSER-FB

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: Fernando Andreu Date: MARCH 21st 2018
Fernando Andreu, Chief Operations Officer

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Means of conformity:

The following product is in conformity with

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Product identification:

Product name: STROMATOLYSER-4DL

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

List of Applied Standards:

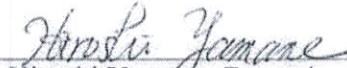
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:


Hiroshi Yamane, Executive Vice President

Date: 13 March, 2018

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:


Fernando Andreu, Chief Operations Officer

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Means of conformity:

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Product identification:

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.

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:

Fernando Andreu Date: MARCH 21ST 2018
Fernando Andreu, Chief Operations Officer

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The following product is in conformity with

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Product identification:

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 Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:


Hiroshi Yamane, Executive Vice President

Date:

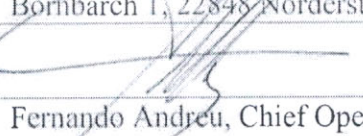
13 March 2018

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:


Fernando Andreu, Chief Operations Officer

Date:

MARCH 21st 2018

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Product identification:

Product name: CELLCLEAN

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
Hiroshi Yamane, Executive Vice President

Date:

13 March 2018

Authorised representative:

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Means of conformity:

The following product is in conformity with

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Product identification:

Product name: e-CHECK(XE)

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

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