



Sysmex Europe GmbH Bornbarch 1 · 22848 Norderstedt Germany

To whom it may concern

Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt, Germany
Phone +49 40 52726-0
Fax +49 40 52726-100
info@sysmex-europe.com

LETTER OF AUTHORIZATION

Whereas Sysmex Europe GmbH ("Sysmex"), who are established, reputable and authorised representative in Europe, Africa and Middle East (EMEA region), officially announced by the manufacturer Sysmex Corporation, having its principal place of business at 1-5-1 Wakinochama Kaigandoori, Chuo-ku, Kobe 651-0073, Japan, and

having the power to grant authorizations to local representatives within the above mentioned markets, do hereby declare that

ECHIPAMED Plus SRL,

Valea Trandafirilor 24 «B», off. 80, MD

Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

To whom it may concern

Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt, Germany
Phone +49 40 52726-0
Fax +49 40 52726-100
info@sysmex-europe.com

DECLARATION

We, Sysmex Europe GmbH, located at Bornbarch 1, 22848 Norderstedt, Germany, who are established, reputable and authorised representative in Europe (EC REP), Africa and Middle East (EMEA region), officially announced by the manufacturer Sysmex Corporation, Japan hereby confirm that our Haematology Analysers

XN-1000, XN-2000, XP-300 and UX-2000

are 'closed systems' and only to be used together with Sysmex Reagents, Sysmex Controls and Sysmex Calibrators. Every change of this closed system by the user is regarded as 'non-specified use' by Sysmex.

The technology of all Sysmex IVD analys

Reagents, Controls and Calibrators that are allowed to be used on Sysmex Haematology Analysers:

XN-1000	XN-2000	XP-300	UX-2000
CELLPACK DCL	CELLPACK DCL	CELLPACK	UX II PACK-BAC
CELLPACK DST	CELLPACK DST	STROMATOLYSER-WH	UX II PACK-SED
CELLPACK DFL	CELLPACK DFL	CELLCLEAN	UX II SEARCH -BAC
Lysercell WDF	Lysercell WDF	EIGHTCHECK-3WP	UX II SEARCH -SED
Lysercell WNR	Lysercell WNR	SCS-1000	UX II SHEATH
Lysercell WPC	Lysercell WPC		UX CLEAN -C
SULFOLYSER	SULFOLYSER		MEDITAPE II 10U
Fluorocell PLT	Fluorocell PLT		MEDITAPE II 9U
Fluorocell RET	Fluorocell RET		MEDITAPE II 10K
Fluorocell WDF	Fluorocell WDF		UF II CONTROL
Fluorocell WNR	Fluorocell WNR		MEDITAPE CHECK 1
Fluorocell WPC	Fluorocell WPC		MEDITAPE CHECK 2
CELLCLEAN	CELLCLEAN		UF II Calibrator
CELLCLEAN AUTO	CELLCLEAN AUTO		
XN CHECK	XN CHECK		
XN CHECK BF	XN CHECK BF		
XN CAL	XN CAL		
XN CAL PF	XN CAL PF		

End of list



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Composition of Sysmex Reagents

The composition of Sysmex Reagents is highly confidential! Therefore only active components and those classified as dangerous must be declared on the product labelling.

The below listed table gives an overview of these components in Sysmex Reagents:

Cellpack	Sodium chloride 6.38 g/L Boric acid 1.0 g/L Sodium tetraborate 0.2 g/L EDTA-2K 0.2 g/L
CELLPACK DCL	Sodium chloride 0.7% Tris buffer 0.2% EDTA-2K 0.02%
CELLPACK DST	Sodium chloride 15.7% Tris buffer 4.3% EDTA-2K 0.4%
CELLPACK DFL	Tricine buffer 0.17%
CELLCLEAN	Sodium Hypochlorite (available chlorine concentration 5.0%)
CELLCLEAN AUTO	Sodium Hypochlorite (available chlorine concentration 5.0%)
Stromatolyser-WH	Organic quaternary ammonium salt 8.5 g/L Sodium chloride 0.6 g/L
Lysercell WDF	Organic quaternary ammonium salts 0.07% Nonionic surfactant 0.17%
Lysercell WNR	Organic quaternary ammonium salts 0.20% Nonionic surfactant 0.10%
Lysercell WPC	Anionic surfactant 0.03% Nonionic surfactant 0.12%
Sulfolyser	Sodium lauryl sulfate 1.7 g/L
Fluorocell PLT	Oxazine 0.003% Ethylene glycol 99.9%
Fluorocell RET	Polymethine 0.03% Methanol 7.9% Ethylene glycol 92.0%
Fluorocell WDF	Polymethine 0.002% Methanol 3.0% Ethylene glycol 96.9%
Fluorocell WNR	Polymethine 0.005% Ethylene glycol 99.9%

Company Location Norderstedt
Registered AG Kiel
HRB 4179
VAT-ID DE 118 687 842
WEEE/ElektroG Reg. Nr. DE 159 56 453

Managing Directors
Fernando Andreu
Kensuke Iizuka
Takeshi Kubota
Kazuya Obe
Dr. Michael Schaefer
Dr. Jürgen Schulze
Matthias Völkel

The Bank of Tokyo-Mitsubishi UFJ, Ltd. Hamburg
Bank ID-Code 300 107 00
Account Nr. 03 77 13
IBAN DE03 3001 0700 0000 0377 13
SWIFT/BIC Code BOTKDE33



Fluorocell WPC	Polymethine 0.004% Ethanol 15.1% Ethylene glycol 84.8%
XN CHECK	quality control material; includes stabilized human red blood cells, human white blood cells, a platelet and nucleated red blood cell component in a preservative medium.
XN CHECK BF	quality control material; includes stabilized human red blood cells and white blood cells in a preservative medium.
XN CAL	calibrator; includes stabilized human red blood cells, human white blood cells, a platelet and nucleated red blood cell component in a preservative medium.
XN CAL PF	calibrator; includes stabilized human red blood cells and a platelet component in a preservative medium.
Eightcheck-3WP	quality control material; includes stabilized human red blood cells, fixed mammalian white blood cells and a platelet component in a preservative medium
SCS-1000	quality control material; contains stabilised human red blood cells, fixed mammalian white bloodcells, and a platelet component in a medium containing preservatives.
UX II PACK-BAC	Buffer 1.9% Cation surfactant 0.1%
UX II PACK-SED	Buffer 2.1%
UX II SEARCH -BAC	Polymethine Dye 0.01% (w / w) Ethylene glycol 99.9% (w / w)
UX II SEARCH -SED	Polymethine Dye 0.03% (w / w) Ethylene glycol 99.9% (w / w)
UX II SHEATH	Tris Buffer 0.14%
UX CLEAN -C	t-Octylphenoxypolyethoxyethanol < 1.0 % Sodium azide < 0.1 % Sodium phosphate tribasic dodecahydrate < 1.0 %
MEDITAPE II 10U	Reactive ingredients (per 100 test strips) [Glucose] Glucose oxidase: 700 I.U., Peroxidase: 175 P.U., 4-Aminoantipyrine: 14.0 mg, 1-Naphthol-3,6-disulfonic acid, disodium salt: 14 mg [Protein] Tetrabromophenol blue: 0.35 mg [Bilirubin] 2-Methyl-5-nitroaniline: 1.9 mg, Sodium nitrite: 1.0 mg [Urobilinogen] 3,3'-Dimethoxy-4,4'-biphenylbis (diazonium tetrafluoroborate): 0.16 mg [Creatinine] 2,6-Dichloro-4'-hydroxy-3',3''-dimethyl-3-sulfofuchson-5',5''-dicarboxylic acid, trisodium salt: 0.34 mg, Palladium (II) chloride: 0.10 mg [pH] Bromocresol green: 0.07 mg, Bromoxyleneol blue: 0.72 mg [Blood] Cumene hydroperoxide: 30.0 mg, 3,3',5,5'-Tetramethylbenzidine: 15.0 mg [Ketones] Sodium nitroprusside: 12.0 mg [Nitrite] Sulfanilamide: 3.9 mg, N-1-Naphthylethylenediamine dihydrochloride: 0.3 mg [Leukocytes] 3-(N-Toluenesulfonyl-L-alanyloxy) indole: 0.69 mg, 2-Methoxy-4-(N-morpholino)benzenediazonium: 0.38 mg

MEDITAPE II 9U	Reactive ingredients (per 100 test strips) [Glucose] Glucose oxidase: 700 I.U., Peroxidase: 175 P.U., 4-Aminoantipyrine: 14.0 mg, 1-Naphthol-3,6-disulfonic acid, disodium salt: 14 mg [Protein] Tetrabromophenol blue: 0.35 mg [Bilirubin] 2-Methyl-5-nitroaniline: 1.9 mg, Sodium nitrite: 1.0 mg [Urobilinogen] 3,3'-Dimethoxy-4,4'-biphenylbis (diazonium tetrafluoroborate): 0.16 mg [pH] Bromocresol green: 0.07 mg, Bromoxyleneol blue: 0.72 mg [Blood] Cumene hydroperoxide: 30.0 mg, 3,3',5,5'-Tetramethylbenzidine: 15.0 mg [Ketones] Sodium nitroprusside: 12.0 mg [Nitrite] Sulfanilamide: 3.9 mg, N-1-Naphthylethylenediamine dihydrochloride: 0.3 mg [Leukocytes] 3-(N-Toluenesulfonyl-L-alanyloxy) indole: 0.69 mg, 2-Methoxy-4-(N-morpholino)benzenediazonium: 0.38 mg	
MEDITAPE II 10K	Reactive ingredients (per 100 test strips) [Glucose] Glucose oxidase: 700 I.U., Peroxidase: 175 P.U., 4-Aminoantipyrine: 14.0 mg [Protein] Tetrabromophenol blue: 0.35 mg [Albumin] 4,5,6,7-Tetrachloro-2',4',5',7'-tetraiodofluorescein disodium salt: 0.14 mg [Bilirubin] 2-Methyl-5-nitroaniline: 1.9 mg, Sodium nitrite: 1.0 mg [Creatinine] 2,6-Dichloro-4'-hydroxy-3',3''-dimethyl-3-sulfofuchson-5',5''-dicarboxylic acid, trisodium salt: 0.34 mg, Palladium (II) chloride: 0.10 mg [pH] Bromocresol green: 0.07 mg, Bromoxyleneol blue: 0.72 mg [Blood] Cumene hydroperoxide: 30.0 mg, 3,3',5,5'-Tetramethylbenzidine: 15.0 mg [Ketones] Sodium nitroprusside: 12.0 mg [Nitrite] Sulfanilamide: 3.9 mg, N-1-Naphthylethylenediamine dihydrochloride: 0.3 mg [Leukocytes] 3-(N-Toluenesulfonyl-L-alanyloxy) indole: 0.69 mg, 2-Methoxy-4-(N-morpholino)benzenediazonium: 0.38 mg	
UF II CONTROL	UF II CONTROL -H Control particles 0.4% (w / w) NOTE : This product contain Latex particle.	UF II CONTROL -L Control particles 0.1% (w / w) NOTE : This product contain Latex particle.
MEDITAPE CHECK 1	prepared from human urine; Chemical and biochemical substances as well as constituents of human origin are contained.	
MEDITAPE CHECK 2	prepared from human urine; Chemical and biochemical substances as well as constituents of human origin are contained.	
UF II Calibrator	Control particles 0.4% (w / w) NOTE : This product contain Latex particle.	

On behalf of Sysmex Europe GmbH



i.A. Katharina Paucke
Manager Regulatory Affairs



sysmex

Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt

Date: January 19th, 2016

Place: 22848 Norderstedt, Germany

„Design and specifications may be subject to changes due to further product development. Changes are confirmed by their appearance on a newer document and verification according to its date of issue.“



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 110072

Certificate Holder:



SYSMEX EUROPE GmbH

Bornbarch 1
22848 Norderstedt
Germany

including the locations according to annex

Scope:

Sales and service of devices, reagents and accessories for in-vitro diagnostics in the area of haematology, urine analytics, coagulation and detection of an epithelial cell marker for the diagnosis of metastases in lymph nodes, as well as of products in the area of laboratory automation and laboratory EDP systems. Design, development and manufacturing of software for in-vitro diagnostic use. Distribution of magnetic sensing devices, probes, associated equipment and sterile magnetic markers. Distribution and servicing of scalp-cooling devices with accessories.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2018-09-06 until 2020-07-24.
First certification 2011

2018-09-13

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln



www.tuv.com



Deutsche
Akkreditierungsstelle
D-ZM-16031-01-00



TÜVRheinland®
Precisely Right.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
SYSMEX EUROPE GmbH
Bornbarch 1
22848 Norderstedt
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-05-17

Certificate Registration No.: SX 60137613 0001

An audit was performed. Report No.: 21245244 005

This Certificate is valid until: 2022-05-16

Certification Body



Date 2019-04-29

TÜV Rheinland LGA Products GmbH - Tillystraße 2 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



S. Hoffmann
Dipl.-Ing. Sven Hoffmann

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: 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: 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

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.

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: UXII PACK-SED

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:

 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.

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: UXII PACK-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

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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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: UX II SEARCH - SED

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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EC Declaration of Conformity

Application of Directives:

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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 II SEARCH -BAC

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

List of Applied Standards:

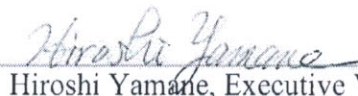
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:


Hiroshi Yamane, Executive Vice President

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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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: 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:


Fernando Andreu, Chief Operations Officer

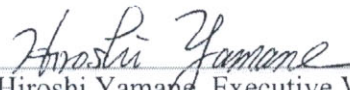
Date: JANUARY 3rd 2018

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: December 28, 2017

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: 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 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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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: CA CLEAN I

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

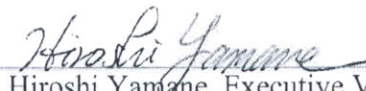
List of Applied Standards:

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

Legal Manufacturer:

Name: SYSMEX CORPORATION

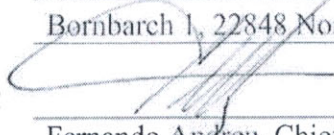
Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

Authorised officer:  Date: 13 March 2018
Hiroshi Yamane, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

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

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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: UFII CONTROL

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: 3 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

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.

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: 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

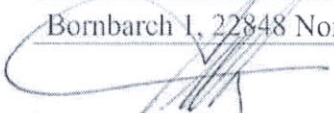
Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

Authorised officer:  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

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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: 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.

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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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: 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:

 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

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