

Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

To whom it may concern

Sysmex Europe GmbH  
Bornbarch 1  
22848 Norderstedt, Germany  
Phone +49 40 527 26-0  
Fax +49 40 527 26-100  
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 Wakinohama-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 the company

**ECHIPAMED Plus SRL**  
**Valea Trandafirilor 24 "B", off. 80**  
**MD-2001 Chisinau, Moldova (the "COMPANY")**

is our distributor and local representative for the following Sysmex products:

**Sysmex Haematology- and Urine- Analysers**  
with Reagents, Accessories, Software and Spare Parts  
(the "**Products**")

In the territory of Moldova (the "**TERRITORY**")

The **COMPANY** is therefore authorized to carry out all commercial and support activities for the **PRODUCTS** including sales, marketing, application, registration and field service support in the **TERRITORY**.

The **COMPANY** is aware that this special authorisation is limited to the above listed **PRODUCTS** and does not create any further rights for the **COMPANY**.

Company Location Norderstedt  
Registered AG Kiel  
HRB 4179  
VAT-ID DE 116 687 842  
WEEE/ElektroG Reg. Nr. DE 159 56 453

Managing Directors  
Alain Baverel  
Seido Biwa  
Alberto Bonadoni  
Kensuke Iizuka  
Iwane Matsui  
Stefanie Schaal  
Jan Willem Schipper  
Matthias Volkel

COMMERZBANK AG, Hamburg  
IBAN DE 20 2004 0000 0287 1879 00  
SWIFT/BIC Code COBADE33XXX

[www.sysmex-europe.com](http://www.sysmex-europe.com)



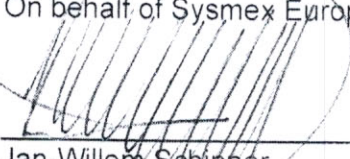


We hereby grant our warranty following our general conditions of sale for the **PRODUCTS** delivered, consisting of and limited to:

Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

This declaration is valid until 31 March 2022 and may be revoked unilaterally by Sysmex in writing before that date for due cause. Such due cause shall, among others, be the termination or expiration of the distributorship relationship, if any, between Sysmex and the **COMPANY**.

On behalf of Sysmex Europe GmbH

  
Jan-Willem Schipper  
Senior Executive Officer

Date: 08 March, 2021

Place: 22848 Norderstedt, Germany



Sysmex Europe GmbH  
Bornbarch 1  
22848 Norderstedt





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 analysers is fine-tuned together with the corresponding reagents used on each single analyser. Thereby, using Sysmex reagents maintains optimum performance as well as optimal and enhanced accuracy of the system. There is a high interdependency between research and using/finding optimal reagents for any new parameter(s). As Sysmex is actively doing research, it is thereby ensured that Sysmex reagents fulfil best practice requirements for any research parameter(s), which later will become diagnostic parameter(s) after the legally required procedures under Annex VIII-IVD-Directive 98/79/EC.

**Therefore Sysmex Reagents offer best performance on Sysmex Analysers.**

The Reagents, Controls and Calibrators listed on the following page are allowed to be used on Sysmex Haematology Analysers.

On behalf of Sysmex Europe GmbH

Date: January 14<sup>th</sup>, 2016

Place: 22848 Norderstedt, Germany

Pandora

**sysmex**  
Sysmex Europe GmbH

i.A. Katharina Paucke  
Manager Regulatory Affairs

„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.”

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





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

| <b>XN-1000</b> | <b>XN-2000</b> | <b>XP-300</b>    | <b>UX-2000</b>    |
|----------------|----------------|------------------|-------------------|
| 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<br>Boric acid 1.0 g/L<br>Sodium tetraborate 0.2 g/L<br>EDTA-2K 0.2 g/L |
| CELLPACK DCL     | Sodium chloride 0.7%<br>Tris buffer 0.2%<br>EDTA-2K 0.02%                                       |
| CELLPACK DST     | Sodium chloride 15.7%<br>Tris buffer 4.3%<br>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<br>Sodium chloride 0.6 g/L                             |
| Lysercell WDF    | Organic quaternary ammonium salts 0.07%<br>Nonionic surfactant 0.17%                            |
| Lysercell WNR    | Organic quaternary ammonium salts 0.20%<br>Nonionic surfactant 0.10%                            |
| Lysercell WPC    | Anionic surfactant 0.03%<br>Nonionic surfactant 0.12%                                           |
| Sulfolyser       | Sodium lauryl sulfate 1.7 g/L                                                                   |
| Fluorocell PLT   | Oxazine 0.003%<br>Ethylene glycol 99.9%                                                         |
| Fluorocell RET   | Polymethine 0.03%<br>Methanol 7.9%<br>Ethylene glycol 92.0%                                     |
| Fluorocell WDF   | Polymethine 0.002%<br>Methanol 3.0%<br>Ethylene glycol 96.9%                                    |
| Fluorocell WNR   | Polymethine 0.005%<br>Ethylene glycol 99.9%                                                     |

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

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

On behalf of Sysmex Europe GmbH

*Paucke*

i.A. Katharina Paucke  
Manager Regulatory Affairs



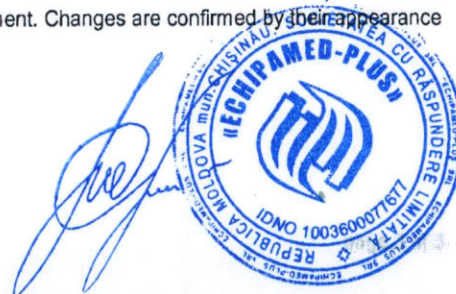
**sysmex**

Sysmex Europe GmbH  
Bornbarch 1  
22848 Norderstedt

Date: January 19<sup>th</sup>, 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

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



# Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 110072**

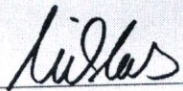
Certificate Holder: **SYSMEX EUROPE GmbH**  
Bornbarch 1  
22848 Norderstedt  
Germany

Scope: Sales, marketing and service of  
in-vitro diagnostic medical devices

Proof has been furnished by means of an audit that the  
requirements of ISO 14001:2015 are met.

Validity: The certificate is valid from 2020-07-25 until 2023-07-24.  
First certification 2011

2020-03-19

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

www.tuv.com



Deutsche  
Akkreditierungsstelle  
D-ZM-16031-01-00





# 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 DCL

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

## List of Applied Standards:

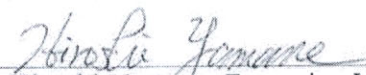
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:

  
Hiroshi Yamane, Executive Vice President

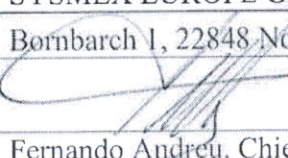
Date: 13 March 2018

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

  
Fernando Andreu, Chief Operations Officer

Date: MARCH 21ST 2018

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: 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 21<sup>st</sup> 2018

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- 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 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:

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 21<sup>ST</sup> 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.



# EC Declaration of Conformity

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- 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

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

Authorised officer:

  
Hiroshi Yamane, Executive Vice President

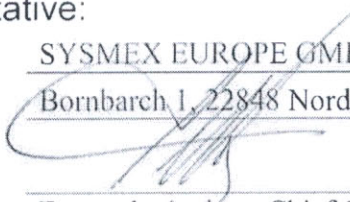
Date: 13 March, 2018

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Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

  
Fernando Andreu, Chief Operations Officer

Date: MARCH 21<sup>st</sup> 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: Fluorocell WNR

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

## List of Applied Standards:

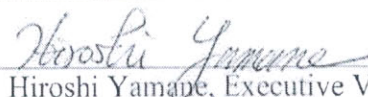
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:

  
Hiroshi Yamane, Executive Vice President

Date:

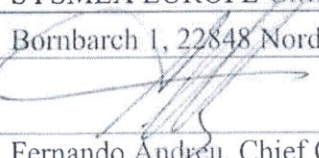
13 March 2018

## 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.



# 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: 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 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 21<sup>ST</sup> 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: 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:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Fernando Andreu, Chief Operations Officer

Date:

MARCH 21<sup>ST</sup> 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.





# 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: 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:

  
Hiroshi Yamane, Executive Vice President

Date:

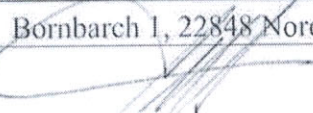
13 March 2018

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

  
Fernando Andreu, Chief Operations Officer

Date:

MARCH 21<sup>st</sup> 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.

# 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: XN CAL

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

## List of Applied Standards:

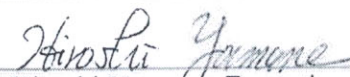
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:



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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