

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 56 459

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

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

www.sysmex-europe.com





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

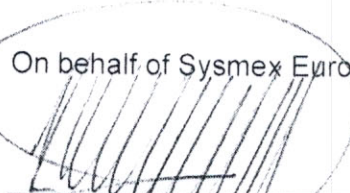
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

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

Date: 08 March, 2021

Place: 22848 Norderstedt, Germany


Jan-Willem Schipper
Senior Executive Officer



Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt



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22848 Norderstedt, Germany
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To whom it may concern

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.

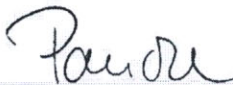
Therefore Sysmex Reagents offer best performance on Sysmex Analysers.

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 14th, 2016

Place: 22848 Norderstedt, Germany



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:

| 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



To whom it may concern

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.

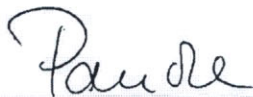
The below listed table gives an overview of these components in Sysmex Reagents:

| | |
|------------------|---|
| 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% |

| | |
|-------------------|--|
| 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-disufonic 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-sulfofuchsone-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-disufonic 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-sulfofuchsone-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

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.

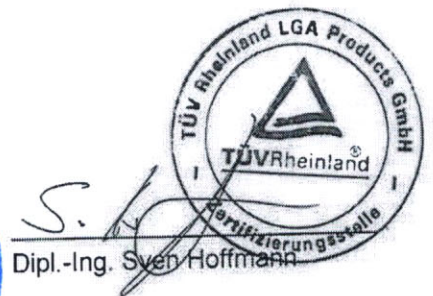
Effective Date: 2019-05-17
Certificate Registration No.: SX 60137613 0001
An audit was performed. Report No.: 21245244 005
This Certificate is valid until: 2022-05-16

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



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: 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 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: 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
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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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: 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 Wakinojama-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: *[Signature]* 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: 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*

Date: 13 March, 2018

Hiroshi Yamane, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: *[Signature]*

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: Fluorocell WNR

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

List of Applied Standards:

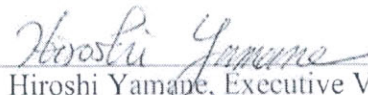
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

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

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Product identification:

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List of Applied Standards:

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

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Fernando Androu Date: MARCH 21ST 2018
Fernando Androu, 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: 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

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 Date: 13 March 2018
Hiroshi Yamane, Executive Vice President

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Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

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Fernando Andreu, Chief Operations Officer

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Means of conformity:

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- 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:

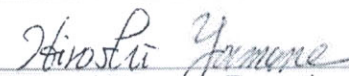
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Authorised officer:



Date:

13 March, 2018

Hiroshi Yamane, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:



Date:

14 March 2018

Fernando Andreu, Chief Operations Officer

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