



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 Wakino-hama-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 118 687 842  
WEEE/ElektroG Reg. Nr. DE 159 56 453

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

COMMERZBANK AG, Hamburg  
IBAN DE20 2004 0000 0287 1879 00  
SWIFT/BIC Code COBADEFFXXX







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## 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.

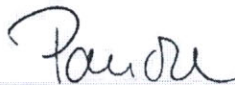
**Therefore Sysmex Reagents offer best performance on Sysmex Analysers.**

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



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  
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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 BOTKDE3X



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:

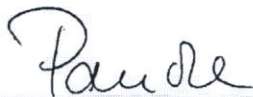
Cellpack	Sodium chloride 6.38 g/L Boric acid 1.0 g/L Sodium tetraborate 0.2 g/L EDTA-2K 0.2 g/L
CELLPACK DCL	Sodium chloride 0.7% Tris buffer 0.2% EDTA-2K 0.02%
CELLPACK DST	Sodium chloride 15.7% Tris buffer 4.3% EDTA-2K 0.4%
CELLPACK DFL	Tricine buffer 0.17%
CELLCLEAN	Sodium Hypochlorite (available 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	<b>Reactive ingredients (per 100 test strips)</b> [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	<b>Reactive ingredients (per 100 test strips)</b> [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	<b>Reactive ingredients (per 100 test strips)</b> [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 19<sup>th</sup>, 2016

Place: 22848 Norderstedt, Germany

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# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **09 100 89004**

Certificate Holder: **SYSMEX CORPORATION**  
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan  
including the locations according to annex

Scope: Development, design, production, sales and servicing of in-vitro diagnostic medical devices, laboratory equipment, reagents and laboratory information system, and development, design, production and sales of customized recombinant protein

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

Validity: The certificate is valid from 2022-05-13 until 2024-07-31.  
First certification 1998

2022-05-13

TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

www.tuv.com





# Certificate



**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1254782-1  
Organization: **SYSMEX CORPORATION**  
1-5-1 Wakinohama-Kaigandori,  
Chuo-ku, Kobe  
651-0073 Japan

Scope: Design and development, manufacture, distribution, installation and service of blood analyzer, urine analyzer, related reagents and accessories  
Product categories: analyzers and reagents for hematological test, blood coagulation test, immune serum test, biochemical test, genetic test, bacteriological test and urine test

In accordance with EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150258788-301  
Effective date: 2022-04-28  
Expiry date: 2024-07-31  
Issue date: 2022-04-28



*M. Aihara*



Michiaki Aihara  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **09 104 9374**

Certificate Holder: **SYSMEX CORPORATION**  
1-5-1 Wakinohama-kaigandori, Chuo-ku, Kobe  
651-0073, Japan

including the locations according to annex

Scope: Development, Design, Production, Sales and Servicing Support of In-vitro Diagnostic Medical Devices, Laboratory Equipment, Reagents and Information Technology Systems for Laboratories and Sales of Customized Recombinant Proteins

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

Validity: The certificate is valid from 2020-04-07 until 2023-04-06.  
First certification 2000

2020-02-25



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln



# EC Declaration of Conformity

## Application of Directives:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

## Means of conformity:

The following product is in conformity with  
- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III of the Directive.

## Product identification:

Product name: CELLPACK

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

## List of Applied Standards:

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

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: Hiroshi Yamane 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: STROMATOLYSER-WH

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 Yamano* Date: 13 March, 2018  
Hiroshi Yamano, 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

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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:

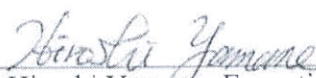
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:



Date:

13 March 2018

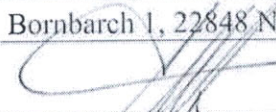
Hiroshi Yamane, Executive Vice President

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:



Date:

MARCH 21<sup>ST</sup> 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: EIGHTCHECK-3WP

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

## List of Applied Standards:

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

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:

Hiroshi Yamane  
Hiroshi Yamane, Executive Vice President

Date: 13 March, 2018

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Fernando Andreu, Chief Operations Officer

Date: MARCH 21st 2018

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until 25.05.2022 or until a revised declaration is issued due to product modifications.

