



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 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 Volkel

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





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

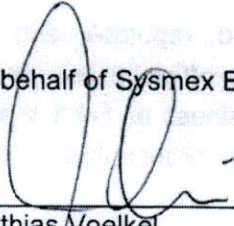
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

This declaration is valid until 31 March 2023 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: 09 February, 2022

Place: 22848 Norderstedt, Germany

  
Matthias Voelkel  
Senior Executive Officer



Sysmex Europe GmbH  
Bornbarch 1  
22848 Norderstedt



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

## DECLARATION

As a responsible representative of Sysmex Europe GmbH, I hereby declare that our Sysmex Haematology Analysers

**XT-2000i, XT-1800i, XS-1000i, XS-800i, XS-500i, pocH-100i, KX-21N and XP-300**

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.

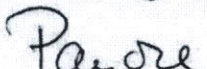
**Therefore Sysmex Reagents offer best performance on Sysmex Analysers.**

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

| XT-2000i           | XT-1800i           | pocH-100i         | XS-1000i           |
|--------------------|--------------------|-------------------|--------------------|
| CELLPACK™          | CELLPACK™          | pocH-pack 65      | CELLPACK™          |
| STROMATOLYSER™-FB  | STROMATOLYSER™-FB  | pocH-pack 65XL    | STROMATOLYSER™-4DS |
| STROMATOLYSER™-4DS | STROMATOLYSER™-4DS |                   | STROMATOLYSER™-4DL |
| STROMATOLYSER™-4DL | STROMATOLYSER™-4DL |                   | SULFOLYSER™        |
| SULFOLYSER™        | SULFOLYSER™        |                   | CELLCLEAN™         |
| RET-SEARCH™ (II)   |                    |                   | e-CHECK™ (XE)      |
| CELLCLEAN™         | CELLCLEAN™         | CELLCLEAN™        | e-CHECK™ (XS)      |
| e-CHECK™ (XE)      | e-CHECK™ (XE)      | EIGHTCHECK™-3WP   | SCS-1000           |
| SCS-1000           | SCS-1000           |                   |                    |
| XS-800i            | XS-500i            | KX-21N            | XP-300             |
| CELLPACK™          | CELLPACK™          | CELLPACK™         | CELLPACK™          |
| STROMATOLYSER™-4DS | STROMATOLYSER™-4DS |                   |                    |
| STROMATOLYSER™-4DL | STROMATOLYSER™-4DL | STROMATOLYSER™-WH | STROMATOLYSER™-WH  |
| SULFOLYSER™        | SULFOLYSER™        |                   |                    |
| CELLCLEAN™         | CELLCLEAN™         | CELLCLEAN™        | CELLCLEAN™         |
| e-CHECK™ (XE)      | e-CHECK™ (XE)      | EIGHTCHECK™-3WP   | EIGHTCHECK™-3WP    |
| e-CHECK™ (XS)      | e-CHECK™ (XS)      |                   |                    |
| SCS-1000           | SCS-1000           | SCS-1000          | SCS-1000           |

With kind regards, on behalf of Sysmex Europe GmbH

Norderstedt, August 30, 2013

  
i.A. Katharina Paucke  
Manager Regulatory Affairs

  
**sysmex**  
Sysmex Europe GmbH

Company Location Norderstedt  
Registered AG Kiel  
HRB 4179  
VAT-ID DE 118 687 842  
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Managing Directors  
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Dr. Michael Schaefer  
Dr. Jürgen Schulze  
Kohei Sumitani  
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

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



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## Composition of Sysmex Reagents

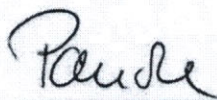
The composition of Sysmex Reagents is highly confidential! Therefore only active components and those classified as dangerous must be declared on the package label.

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

|                                    |                                                                                                                                                                                                                                                                                                                                                                                      |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------------------|----------------------------|--------------------------|----------------------|------------------------------------|------------------------------|--|-------------------|--|
| CELLPACK™                          | SODIUM CHLORIDE 6.4 G/L (=0.64 %)<br>BORIC ACID 1.0 G/L (=0.10 %)<br>SODIUM TETRABORATE 0.2 G/L (=0.02 %)<br>EDTA-2K 0.2 G/L (=0.02 %)                                                                                                                                                                                                                                               |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| CELLCLEAN™                         | SODIUM HYPOCHLORITE (AVAILABLE CONCENTRATION 5.0 %)                                                                                                                                                                                                                                                                                                                                  |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| POCH-PACK 65 AND<br>POCH-PACK 65XL | <table border="1"> <tr> <td><b>DILUENT (BLUE)</b></td><td><b>LYSING REAGENT (PURPLE)</b></td></tr> <tr> <td>• SODIUM CHLORIDE 6.38 G/L</td><td>• SODIUM CHLORIDE 0.6G/L</td></tr> <tr> <td>• BORIC ACID 1.0 G/L</td><td>• ORG. QUART. AMMONIUMSALT, 8.5G/L</td></tr> <tr> <td>• SODIUM TETRABORATE 0.2 G/L</td><td></td></tr> <tr> <td>• EDTA-2K 0.2 G/L</td><td></td></tr> </table> | <b>DILUENT (BLUE)</b> | <b>LYSING REAGENT (PURPLE)</b> | • SODIUM CHLORIDE 6.38 G/L | • SODIUM CHLORIDE 0.6G/L | • BORIC ACID 1.0 G/L | • ORG. QUART. AMMONIUMSALT, 8.5G/L | • SODIUM TETRABORATE 0.2 G/L |  | • EDTA-2K 0.2 G/L |  |
| <b>DILUENT (BLUE)</b>              | <b>LYSING REAGENT (PURPLE)</b>                                                                                                                                                                                                                                                                                                                                                       |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| • SODIUM CHLORIDE 6.38 G/L         | • SODIUM CHLORIDE 0.6G/L                                                                                                                                                                                                                                                                                                                                                             |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| • BORIC ACID 1.0 G/L               | • ORG. QUART. AMMONIUMSALT, 8.5G/L                                                                                                                                                                                                                                                                                                                                                   |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| • SODIUM TETRABORATE 0.2 G/L       |                                                                                                                                                                                                                                                                                                                                                                                      |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| • EDTA-2K 0.2 G/L                  |                                                                                                                                                                                                                                                                                                                                                                                      |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| STROMATOLYSER™-FB                  | NON-IONIC SURFACTANT 0.40%<br>ORGANIC QUATERNARY AMMONIUM SALT 0.1%                                                                                                                                                                                                                                                                                                                  |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| STROMATOLYSER™-4DS                 | POLYMETHINE DYE 0.002%<br>METHANOL 3.00%<br>ETHYLENE GLYCOL 96.90%                                                                                                                                                                                                                                                                                                                   |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| STROMATOLYSER™-4DL                 | NON-IONIC SURFACTANT 0.18%<br>ORGANIC QUATERNARY AMMONIUM SALT 0.08%                                                                                                                                                                                                                                                                                                                 |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| STROMATOLYSER™-WH                  | ORGANIC QUATERNARY AMMONIUMSALT 8.5 G/L (=0.85 %)<br>SODIUM CHLORIDE 0.5 G/L (=0.05 %)                                                                                                                                                                                                                                                                                               |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| SULFOLYSER™                        | SODIUM LAURYL SULPHATE 0.17%                                                                                                                                                                                                                                                                                                                                                         |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| RET-SEARCH™ (II)                   | DILUENT: TRICINE BUFFER 0.18%<br>DYE: POLYMETHINE DYE 0.03%<br>METHANOL 7.1%<br>IN ETHYLENE GLYCOL 92.8%                                                                                                                                                                                                                                                                             |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| e-CHECK™ (XE)                      | QUALITY CONTROL MATERIAL, CONTAINS STABILIZED HUMAN AND ANIMAL BLOOD                                                                                                                                                                                                                                                                                                                 |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| e-CHECK™ (XS)                      | QUALITY CONTROL MATERIAL; CONTAINS STABILIZED HUMAN RED BLOOD CELLS                                                                                                                                                                                                                                                                                                                  |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| EIGHTCHECK™-3WP                    | QUALITY CONTROL MATERIAL; CONTAINS STABILIZED HUMAN RED BLOOD CELLS                                                                                                                                                                                                                                                                                                                  |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |
| SCS-1000                           | QUALITY CONTROL MATERIAL; CONTAINS STABILIZED HUMAN RED BLOOD CELLS                                                                                                                                                                                                                                                                                                                  |                       |                                |                            |                          |                      |                                    |                              |  |                   |  |

With kind regards,  
on behalf of Sysmex Europe GmbH

Norderstedt, August 30, 2013



I.A. Katharina Paucke  
Manager Regulatory Affairs



Sysmex Europe GmbH

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IBAN DE03 3001 0700 0000 0377 13  
SWIFT/BIC Code BOTKDE33



# Certificate

Standard **ISO 9001:2015**

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

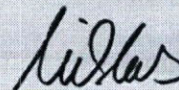
Certificate Holder: **SYSMEX CORPORATION**  
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan  
including the locations according to annex

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

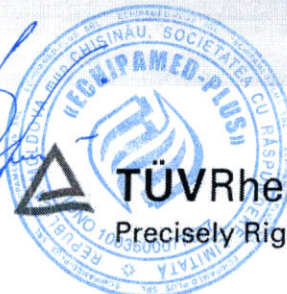


TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

www.tuv.com



Deutsche  
Akkreditierungsstelle  
D-ZM-16031-01-00



**TÜVRheinland®**  
Precisely Right.

# 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

www.tuv.com



Deutsche  
Akkreditierungsstelle  
D-ZM-16031-01-00



**TÜVRheinland®**  
Precisely Right.

# EC Declaration of Conformity

## Application of Directives:

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

## Means of conformity:

The following product is in conformity with

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

## Product identification:

Product name: CELLPACK

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

## List of Applied Standards:

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

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:

Hiroshi Yamane  
Hiroshi Yamane, Executive Vice President

Date: 13 March, 2018

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Fernando Andreu, Chief Operations Officer

Date: MARCH 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: STROMATOLYSER-4DL

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

## List of Applied Standards:

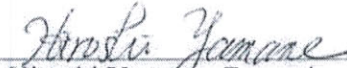
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:

  
Hiroshi Yamane, Executive Vice President

Date: 13 March, 2018

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

  
Fernando Andreu, Chief Operations Officer

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: STROMATOLYSER-4DS

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

## List of Applied Standards:

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

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:

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

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

*Fernando Andreu* Date: MARCH 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: SULFOLYSER

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

## List of Applied Standards:

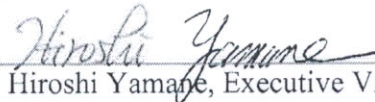
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## 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:

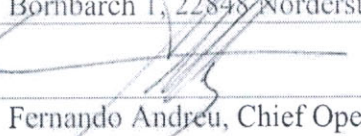
13 March 2018

## 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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# 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, Executive Vice President

Date:

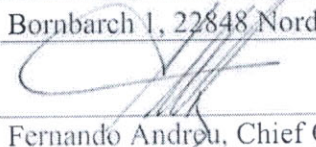
13 March 2018

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Fernando Andreu, Chief Operations Officer

Date:

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