



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 Bonadini
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

www.sysmex-europe.com





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

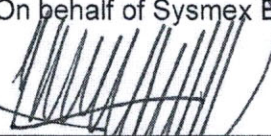
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

This declaration is valid until 31.03.2021 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: March 20th, 2020

Place: 22848 Norderstedt, Germany


Jan-Willem Schipper
Senior Executive Officer



Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt



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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.

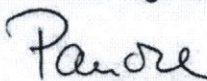
Therefore Sysmex Reagents offer best performance on Sysmex Analysers.

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 Europe GmbH

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

The Bank of Tokyo-Mitsubishi UFJ, Ltd. Hamburg
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SWIFT/BIC Code BOTKDE33

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Composition of Sysmex Reagents

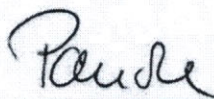
The composition of Sysmex Reagents is highly confidential! Therefore only active components and those classified as dangerous must be declared on the package label.

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

| | | | | | | | | | | | |
|------------------------------------|--|-----------------------|--------------------------------|----------------------------|--------------------------|----------------------|---------------------------------------|------------------------------|--|-------------------|--|
| CELLPACK™ | SODIUM CHLORIDE 6.4 G/L (=0.64 %) BORIC ACID 1.0 G/L (=0.10 %) SODIUM TETRABORATE 0.2 G/L (=0.02 %) EDTA-2K 0.2 G/L (=0.02 %) | | | | | | | | | | |
| CELLCLEAN™ | SODIUM HYPOCHLORITE (AVAILABLE CONCENTRATION 5.0 %) | | | | | | | | | | |
| POCH-PACK 65 AND POCH-PACK 65XL | <table border="1"> <tr> <td>DILUENT (BLUE)</td> <td>LYSING REAGENT (PURPLE)</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> | DILUENT (BLUE) | LYSING REAGENT (PURPLE) | • 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 | |
| DILUENT (BLUE) | LYSING REAGENT (PURPLE) | | | | | | | | | | |
| • 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% ORGANIC QUATERNARY AMMONIUM SALT 0.1% | | | | | | | | | | |
| STROMATOLYSER™-4DS | POLYMETHINE DYE 0.002% METHANOL 3.00% ETHYLENE GLYCOL 96.90% | | | | | | | | | | |
| STROMATOLYSER™-4DL | NON-IONIC SURFACTANT 0.18% ORGANIC QUATERNARY AMMONIUM SALT 0.08% | | | | | | | | | | |
| STROMATOLYSER™-WH | ORGANIC QUATERNARY AMMONIUMSALT 8.5 G/L (=0.85 %) SODIUM CHLORIDE 0.5 G/L (=0.05 %) | | | | | | | | | | |
| SULFOLYSER™ | SODIUM LAURYL SULPHATE 0.17% | | | | | | | | | | |
| RET-SEARCH™ (II) | DILUENT: TRICINE BUFFER 0.18% DYE: POLYMETHINE DYE 0.03% METHANOL 7.1% 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



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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 110072

Certificate Holder:



SYSMEX EUROPE GmbH

Bornbarch 1
22848 Norderstedt
Germany

including the locations according to annex

Scope:

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

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

Validity:

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

2018-09-13

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln



www.tuv.com



Deutsche
Akkreditierungsstelle
D-ZM-16031-01-00



TÜVRheinland®
Precisely Right.



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

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

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

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

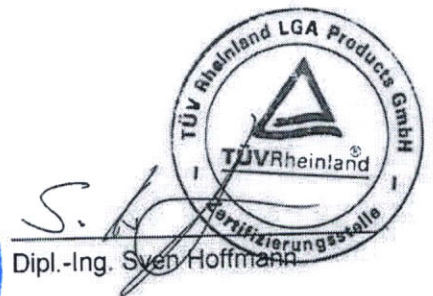
Effective Date: 2019-05-17
Certificate Registration No.: SX 60137613 0001
An audit was performed. Report No.: 21245244 005
This Certificate is valid until: 2022-05-16

Certification Body



Date 2019-04-29

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



S. Hoffmann
Dipl.-Ing. Sven Hoffmann

EC Declaration of Conformity

Application of Directives:

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

Means of conformity:

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

Product identification:

Product name: 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: *[Signature]* 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: 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 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: CELLCLEAN

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

List of Applied Standards:

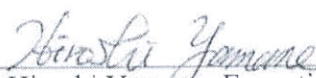
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:



Date:

13 March 2018

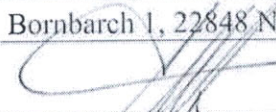
Hiroshi Yamane, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:



Date:

MARCH 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: 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* 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

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.

