To whom it may concern

# 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

**ECHIPAMED Plus SRL,**

Valea Trandafirilor 24 «B», off. 80, MD-2001 Chisinau, Moldova is our distributor and local representative in the territory of Republic of Moldova (the "**COMPANY**")

for the following Sysmex products:

**Sysmex Haematology- and Urine Analysers**
Reagents, Accessories, Software and spare parts (the "**PRODUCTS**").

in the territory of Republic 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**.

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 31.03.2019 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

Sysmex Europe GmbH

Date: March 28th, 2018
Place: DE-22848 Norderstedt

SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" mun. CHISINAU

Sysmex Europe GmbH
Bornbarch 1, 22848 Norderstedt
Phone +49 40 52726-0
Fax +49 40 52726-100
www.sysmex-europe.com

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
Alain Baverel
Seido Biwa
Alberto Bonacini
Kensuke Iizuka
Kazuya Obe
Jan-Willem Schipper
Dr. Jürgen Schulze
Matthias Völkel

The Bank of Tokyo-Mitsubishi UFJ, Ltd. Hamburg
Bank ID-Code 300 107 00
Account Nr. 0377 13
IBAN DE03 3001 0700 0000 0377 13
SWIFT/BIC Code BOTKDEFX

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

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

Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

**Sysmex Europe GmbH**
Bornbarch 1
22848 Norderstedt, Germany
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info@sysmex-europe.com

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 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 POCH-PACK 65XL | **DILUENT (BLUE)**<br>• 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 | **LYSING REAGENT (PURPLE)**<br>• SODIUM CHLORIDE 0.6G/L<br>• ORG. QUART. AMMONIUMSALT, 8.5G/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

# 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

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜV Rheinland®
Precisely Right.

TÜVRheinland®

# 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:

**Details see attachment**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012**
**EN ISO 13485:2012/AC:2012**

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

| | |
|---|---|
| Effective Date: | 2016-05-17 |
| Certificate Registration No.: | SX 60109566 0001 |
| An audit was performed. Report No.: | 21245244 002 |
| This Certificate is valid until: | 2019-05-16 |

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2016-05-17

Dipl.-Ing. C. Wiora

**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

# *EC Declaration of Conformity*

## Application of Council Directive:

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)

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: _____ Date: 31.1.2014

Kohei Sumitani, Managing Director

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: _____ Date: Jan. 23, 2014

Keiji Fujimoto, Executive Officer

Sysmex Corporation
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Tel. +81-78-265-0500 Fax. +81-78-265-0524

# *EC Declaration of Conformity*

## Application of Council Directive:

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)

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: _____ Date: 31.1.2014

Kohei Sumitani, Managing Director

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: _____ Date: Jan. 23, 2014

Keiji Fujimoto, Executive Officer

Sysmex Corporation
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Tel. +81-78-265-0500 Fax. +81-78-265-0524

# *EC Declaration of Conformity*

## Application of Council Directive:

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)

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: _____ Date: 31. 1. 2014

Kohei Sumitani, Managing Director

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: _____ Date: Jan. 23, 2014

Keiji Fujimoto, Executive Officer

Sysmex Corporation
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Tel. +81-78-265-0500 Fax. +81-78-265-0524
www.sysmex.co.jp

# *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) |

## Authorised representative:

| | |
|---|---|
| Name: | SYSMEX EUROPE GMBH |
| Address: | Bornbarch 1, 22848 Norderstedt, Germany |

Authorised officer: Takeshi Kubota Date: 10. Aug. 2015
Takeshi Kubota, Managing Director

## Legal Manufacturer:

| | |
|---|---|
| Name: | SYSMEX CORPORATION |
| Address: | 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan |

Authorised officer: Hiroshi Yamane Date: 14 July, 2015
Hiroshi Yamane, Executive Vice President

Sysmex Corporation
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Tel. +81-78-265-0500 Fax. +81-78-265-0524