



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





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

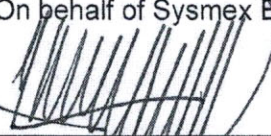
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

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.

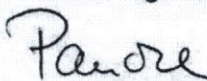
**Therefore Sysmex Reagents offer best performance on Sysmex Analysers.**

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  
WEEE/ElektroG Reg. Nr. DE 159 56 453

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  
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

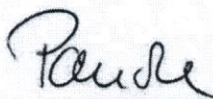
The composition of Sysmex Reagents is highly confidential! Therefore only active components and those classified as dangerous must be declared on the package label.

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

CELLPACK™	SODIUM CHLORIDE 6.4 G/L (=0.64 %) 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><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	
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• 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



Sysmex Europe GmbH

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SWIFT/BIC Code BOTKDE33







# 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.

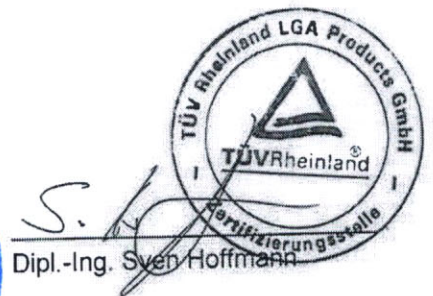
Effective Date: 2019-05-17  
Certificate Registration No.: SX 60137613 0001  
An audit was performed. Report No.: 21245244 005  
This Certificate is valid until: 2022-05-16

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:

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: *[Signature]* 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: CELLCLEAN

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

## List of Applied Standards:

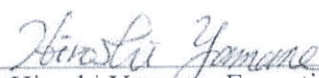
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:



Date:

13 March 2018

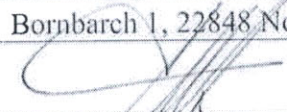
Hiroshi Yamane, Executive Vice President

## 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:

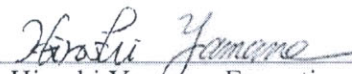
- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:



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, Chief Operations Officer

Date: MARCH 21st 2018

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