sysmex

Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

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

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 (the **"COMPANY"**)

is our distributor and local representative 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 31.03.2020 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
Sysmex Europe GmbH
Bornbarch 1
22848 Norderstedt

Date: April 16, 2019
Place: 22848 Norderstedt

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
Kazuya Oka
Jan-Willem Schipper
Matthias Völkel

MUFG Bank (Europe) N.V. Hamburg
Bank ID-Code 300 107 00
Account Nr. 03 77 13
IBAN DE03 3001 0700 0000 0377 13
SWIFT/BIC [illegible]DEDX

Digitally signed by Turchevici Valeriu
Date: 2019.11.20 18:52:35 EET
Reason: MoldSign Signature
Location: Moldova

ECHIPAMED-PLUS

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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

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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	**DILUENT (BLUE)** • SODIUM CHLORIDE 6.38 G/L • BORIC ACID 1.0 G/L • SODIUM TETRABORATE 0.2 G/L • EDTA-2K 0.2 G/L	**LYSING REAGENT (PURPLE)** • SODIUM CHLORIDE 0.6G/L • ORG. QUART. AMMONIUMSALT, 8.5G/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

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

TÜVRheinland®
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 establisned 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

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2019-04-29

Dipl.-Ing. Sven Hoffmann

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

Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 110072**

Certificate Holder:

SYSMEX EUROPE GmbH
Bornbarch 1
22848 Norderstedt
Germany

including the location
Sysmex Deutschland GmbH
Bornbarch 1
22848 Norderstedt
Germany

Scope: Sales, marketing and service of in vitro diagnostic medical devices

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

Validity: The certificate is valid from 2017-07-25 until 2020-07-24.
First certification 2011

2018-02-12

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

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