

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  
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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 COBADE33XXX

www.sysmex-europe.com





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

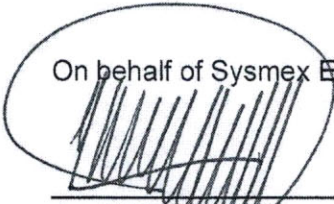
Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

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 · Germany

To whom it may concern

Sysmex Europe GmbH

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info@sysmex-europe.com

## DECLARATION

We, Sysmex Europe GmbH, located at Bornbarch 1, 22848 Norderstedt, Germany, who are established, reputable and authorised representative in Europe (EC REP), Africa and Middle East (EMEA region), officially announced by the manufacturer Sysmex Corporation, Japan hereby confirm that our Haematology Analysers

## XN-1000, XN-2000, XP-300 and UX-2000

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 Reagents, Controls and Calibrators listed on the following page are allowed to be used on Sysmex Haematology Analysers.

On behalf of Sysmex Europe GmbH

Date: January 14<sup>th</sup>, 2016

Place: 22848 Norderstedt, Germany

Pandora

**sysmex**  
Sysmex Europe GmbH

i.A. Katharina Paucke  
Manager Regulatory Affairs

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Company Location Norderstedt  
Registered AG Kiel  
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**Managing Directors**  
Fernando Andreu  
Kensuke Iizuka  
Takeshi Kubota  
Kazuya Obe  
Dr. Michael Schaefer  
Dr. Jürgen Schulze  
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



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

<b>XN-1000</b>	<b>XN-2000</b>	<b>XP-300</b>	<b>UX-2000</b>
CELLPACK DCL	CELLPACK DCL	CELLPACK	UX II PACK-BAC
CELLPACK DST	CELLPACK DST	STROMATOLYSER-WH	UX II PACK-SED
CELLPACK DFL	CELLPACK DFL	CELLCLEAN	UX II SEARCH -BAC
Lysercell WDF	Lysercell WDF	EIGHTCHECK-3WP	UX II SEARCH -SED
Lysercell WNR	Lysercell WNR	SCS-1000	UX II SHEATH
Lysercell WPC	Lysercell WPC		UX CLEAN -C
SULFOLYSER	SULFOLYSER		MEDITAPE II 10U
Fluorocell PLT	Fluorocell PLT		MEDITAPE II 9U
Fluorocell RET	Fluorocell RET		MEDITAPE II 10K
Fluorocell WDF	Fluorocell WDF		UF II CONTROL
Fluorocell WNR	Fluorocell WNR		MEDITAPE CHECK 1
Fluorocell WPC	Fluorocell WPC		MEDITAPE CHECK 2
CELLCLEAN	CELLCLEAN		UF II Calibrator
CELLCLEAN AUTO	CELLCLEAN AUTO		
XN CHECK	XN CHECK		
XN CHECK BF	XN CHECK BF		
XN CAL	XN CAL		
XN CAL PF	XN CAL PF		

End of list





Fluorocell WPC	Polymethine 0.004% Ethanol 15.1% Ethylene glycol 84.8%
XN CHECK	quality control material; includes stabilized human red blood cells, human white blood cells, a platelet and nucleated red blood cell component in a preservative medium.
XN CHECK BF	quality control material; includes stabilized human red blood cells and white blood cells in a preservative medium.
XN CAL	calibrator; includes stabilized human red blood cells, human white blood cells, a platelet and nucleated red blood cell component in a preservative medium.
XN CAL PF	calibrator; includes stabilized human red blood cells and a platelet component in a preservative medium.
Eightcheck-3WP	quality control material; includes stabilized human red blood cells, fixed mammalian white blood cells and a platelet component in a preservative medium
SCS-1000	quality control material; contains stabilised human red blood cells, fixed mammalian white bloodcells, and a platelet component in a medium containing preservatives.
UX II PACK-BAC	Buffer 1.9% Cation surfactant 0.1%
UX II PACK-SED	Buffer 2.1%
UX II SEARCH -BAC	Polymethine Dye 0.01% ( w / w ) Ethylene glycol 99.9% ( w / w )
UX II SEARCH -SED	Polymethine Dye 0.03% ( w / w ) Ethylene glycol 99.9% ( w / w )
UX II SHEATH	Tris Buffer 0.14%
UX CLEAN -C	t-Octylphenoxypolyethoxyethanol < 1.0 % Sodium azide < 0.1 % Sodium phosphate tribasic dodecahydrate < 1.0 %
MEDITAPE II 10U	<b>Reactive ingredients (per 100 test strips)</b> [Glucose] Glucose oxidase: 700 I.U., Peroxidase: 175 P.U., 4-Aminoantipyrine: 14.0 mg, 1-Naphthol-3,6-disulfonic acid, disodium salt: 14 mg [Protein] Tetrabromophenol blue: 0.35 mg [Bilirubin] 2-Methyl-5-nitroaniline: 1.9 mg, Sodium nitrite: 1.0 mg [Urobilinogen] 3,3'-Dimethoxy-4,4'-biphenylbis (diazonium tetrafluoroborate): 0.16 mg [Creatinine] 2,6-Dichloro-4'-hydroxy-3',3''-dimethyl-3-sulfofuchson-5',5''-dicarboxylic acid, trisodium salt: 0.34 mg, Palladium (II) chloride: 0.10 mg [pH] Bromocresol green: 0.07 mg, Bromoxyleneol blue: 0.72 mg [Blood] Cumene hydroperoxide: 30.0 mg, 3,3',5,5'-Tetramethylbenzidine: 15.0 mg [Ketones] Sodium nitroprusside: 12.0 mg [Nitrite] Sulfanilamide: 3.9 mg, N-1-Naphthylethylenediamine dihydrochloride: 0.3 mg [Leukocytes] 3-(N-Toluenesulfonyl-L-alanyloxy) indole: 0.69 mg, 2-Methoxy-4-(N-morpholino)benzenediazonium: 0.38 mg

MEDITAPE II 9U	<b>Reactive ingredients (per 100 test strips)</b> [Glucose] Glucose oxidase: 700 I.U., Peroxidase: 175 P.U., 4-Aminoantipyrine: 14.0 mg, 1-Naphthol-3,6-disulfonic acid, disodium salt: 14 mg [Protein] Tetrabromophenol blue: 0.35 mg [Bilirubin] 2-Methyl-5-nitroaniline: 1.9 mg, Sodium nitrite: 1.0 mg [Urobilinogen] 3,3'-Dimethoxy-4,4'-biphenylbis (diazonium tetrafluoroborate): 0.16 mg [pH] Bromocresol green: 0.07 mg, Bromoxyleneol blue: 0.72 mg [Blood] Cumene hydroperoxide: 30.0 mg, 3,3',5,5'-Tetramethylbenzidine: 15.0 mg [Ketones] Sodium nitroprusside: 12.0 mg [Nitrite] Sulfanilamide: 3.9 mg, N-1-Naphthylethylenediamine dihydrochloride: 0.3 mg [Leukocytes] 3-(N-Toluenesulfonyl-L-alanyloxy) indole: 0.69 mg, 2-Methoxy-4-(N-morpholino)benzenediazonium: 0.38 mg	
MEDITAPE II 10K	<b>Reactive ingredients (per 100 test strips)</b> [Glucose] Glucose oxidase: 700 I.U., Peroxidase: 175 P.U., 4-Aminoantipyrine: 14.0 mg [Protein] Tetrabromophenol blue: 0.35 mg [Albumin] 4,5,6,7-Tetrachloro-2',4',5',7'-tetraiodofluorescein disodium salt: 0.14 mg [Bilirubin] 2-Methyl-5-nitroaniline: 1.9 mg, Sodium nitrite: 1.0 mg [Creatinine] 2,6-Dichloro-4'-hydroxy-3',3''-dimethyl-3-sulfofuchson-5',5''-dicarboxylic acid, trisodium salt: 0.34 mg, Palladium (II) chloride: 0.10 mg [pH] Bromocresol green: 0.07 mg, Bromoxyleneol blue: 0.72 mg [Blood] Cumene hydroperoxide: 30.0 mg, 3,3',5,5'-Tetramethylbenzidine: 15.0 mg [Ketones] Sodium nitroprusside: 12.0 mg [Nitrite] Sulfanilamide: 3.9 mg, N-1-Naphthylethylenediamine dihydrochloride: 0.3 mg [Leukocytes] 3-(N-Toluenesulfonyl-L-alanyloxy) indole: 0.69 mg, 2-Methoxy-4-(N-morpholino)benzenediazonium: 0.38 mg	
UF II CONTROL	UF II CONTROL -H Control particles 0.4% ( w / w ) NOTE : This product contain Latex particle.	UF II CONTROL -L Control particles 0.1% ( w / w ) NOTE : This product contain Latex particle.
MEDITAPE CHECK 1	prepared from human urine; Chemical and biochemical substances as well as constituents of human origin are contained.	
MEDITAPE CHECK 2	prepared from human urine; Chemical and biochemical substances as well as constituents of human origin are contained.	
UF II Calibrator	Control particles 0.4% ( w / w ) NOTE : This product contain Latex particle.	

On behalf of Sysmex Europe GmbH



i.A. Katharina Paucke  
Manager Regulatory Affairs



**sysmex**

Sysmex Europe GmbH  
Bornbarch 1  
22848 Norderstedt

Date: January 19<sup>th</sup>, 2016

Place: 22848 Norderstedt, Germany

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# 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

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Dipl.-Ing. Sven Hoffmann