

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.

Schipper

Senior Executive Officer

Date: March 28th, 2018

Place: DE-22848 Norderstedt

Sysmex Europe GmbH

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 Director Fernando Andrei Alain Bayerel Seido Riwa Alberto Bonacini

Kensuke lizuka

Kazuya Obe Jan-Willem Schipper Dr. Jürgen Schulze Matthias Völkel

Bank ID-Code 390 107 00 Account Nr. 03 77-13 IBAN DE03 3001 0700 0000 0377 13

SWIFT/BIC Code BOTKDEDX



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

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.

Sysmex Europe GmbH

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

On behalf of Sysmex Europe God

Date: January 14th, 2016

Place: 22848 Norderstedt, Germany

i.A. Katharina Paucke

Manager Regulatory Affairs

"Design and specifications may be subject to changes due to further product development. Changes are confirmed by their appearance on a newer document and verification according to its date of issue."





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

XN-1000	XN-2000	XP-300	UX-2000
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	A A VIII A STATE OF THE STATE O	MEDITAPE II 9U
Fluorocell RET	Fluorocell RET	higher than the same of the same	MEDITAPE II 10K
Fluorocell WDF	Fluorocell WDF		UF II CONTROL
Fluorocell WNR	Fluorocell WNR		MEDITAPE CHECK 1
Fluorocell WPC	Fluorocell WPC	The second secon	MEDITAPE CHECK 2
CELLCLEAN	CELLCLEAN	SHAPE OF THE STATE OF	UF II Calibrator
CELLCLEAN AUTO	CELLCLEAN AUTO		Treatment Carbon Colo
XN CHECK	XN CHECK		
XN CHECK BF	XN CHECK BF	NAME OF THE PERSON OF THE PERS	(1) 2 种 (1) 种 (1) (1) (1)
XN CAL	XN CAL		
XN CAL PF	XN CAL PF	management was the supply	STATE OF STATE OF STATES

End of list





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

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 product labelling.

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

Cellpack	Sodium chloride 6.38 g/L Boric acid 1.0 g/L Sodium tetraborate 0.2 g/L EDTA-2K 0.2 g/L
CELLPACK DCL	Sodium chloride 0.7% Tris buffer 0.2% EDTA-2K 0.02%
CELLPACK DST	Sodium chloride 15.7% Tris buffer 4.3% EDTA-2K 0.4%
CELLPACK DFL	Tricine buffer 0.17%
CELLCLEAN	Sodium Hypochlorite (available chlorine concentration 5.0%)
CELLCLEAN AUTO	Sodium Hypochlorite (available chlorine concentration 5.0%)
Stromatolyser-WH	Organic quaternary ammonium salt 8.5 g/L Sodium chloride 0.6 g/L
Lysercell WDF	Organic quaternary ammonium salts 0.07% Nonionic surfactant 0.17%
Lysercell WNR	Organic quaternary ammonium salts 0.20% Nonlonic surfactant 0.10%
Lysercell WPC	Anionic surfactant 0.03% Nonionic surfactant 0.12%
Sulfolyser	Sodium lauryl sulfate 1.7 g/L
Fluorocell PLT	Oxazine 0.003% Ethylene glycol 99.9%
Fluorocell RET	Polymethine 0.03% Methanol 7.9% Ethylene glycol 92.0%
Fluorocell WDF	Polymethine 0.002% Methanol 3.0% Ethylene glycol 96.9%
Fluorocell WNR	Polymethine 0.005% Ethylene glycol 99.9%



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 Kensuke lizuka 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 BOTKDEDX





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 %			
	Reactive ingredients (per 100 test strips)			
	[Glucose] Glucose oxidase: 700 I.U., Peroxidase: 175 P.U., 4-Aminoantipyrine: 14.0 mg, 1-Naphthol-3,6-disufonic 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			
MEDITAPE II 10U	[Creatinine] 2,6-Dichloro-4'-hydroxy-3',3"-dimethyl-3-sulfofuchsone-5',5"-dicarboxylic acid, trisodium salt: 0.34 mg, Palladium (II) chloride: 0.10 mg			
	[pH] Bromocresol green: 0.07 mg, Bromoxylenol 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			





	Reactive ingredients (per 100 test strip	os)				
	[Glucose] Glucose oxidase: 700 I.U., Peroxidase: 175 P.U., 4-Aminoantipyrine: 14.0 mg, 1-Naphthol-3,6-disufonic acid, disodium salt: 14 mg					
	[Protein] Tetrabromophenol blue: 0.35 mg	g				
	[Bilirubin] 2-Methyl-5-nitroaniline: 1.9 mg,	Sodium nitrite: 1.0 mg				
	[Urobilinogen] 3,3'-Dimethoxy-4,4'-bipher	nylbis (diazonium tetrafluoroborate): 0.16 mg				
MEDITAPE II 9U	[pH] Bromocresol green: 0.07 mg, Bromo	exylenol blue: 0.72 mg				
	[Blood] Cumene hydroperoxide: 30.0 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-Naphi	thylethylenediamine dihydrochloride: 0.3 mg				
	[Leukocytes] 3-(N-Toluenesulfonyl-L-alar morpholino)benzenediazonium: 0.38 mg	nyloxy) indole: 0.69 mg, 2-Methoxy-4-(N-				
	Reactive ingredients (per 100 test strip	M = T = 1				
	[Glucose] Glucose oxidase: 700 I.U., Per 4-Aminoantipyrine: 14.0 mg	oxidase: 175 P.U.,				
	[Protein] Tetrabromophenol blue: 0.35 mg	9				
	[Albumin] 4,5,6,7-Tetrachloro-2',4',5',7'-te	[Albumin] 4,5,6,7-Tetrachloro-2',4',5',7'-tetraiodoflurescein disodium salt: 0.14 mg				
	[Bilirubin] 2-Methyl-5-nitroaniline: 1.9 mg, Sodium nitrite: 1.0 mg					
MEDITAPE II 10K	[Creatinine] 2,6-Dichloro-4'-hydroxy-3',3"-dimethyl-3-sulfofuchsone-5',5"-dicarboxylic acid, trisodium salt: 0.34 mg, Palladium (II) chloride: 0.10 mg					
	[pH] Bromocresol green: 0.07 mg, Bromoxylenol 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-alan morpholino)benzenediazonium: 0.38 mg	[Leukocytes] 3-(N-Toluenesulfonyl-L-alanyloxy) indole: 0.69 mg, 2-Methoxy-4-(N-morpholino)benzenediazonium: 0.38 mg				
	UFII CONTROL -H	UF II CONTROL -L				
UF II CONTROL	Control particles 0.4% (w / w) NOTE: This product contain Latex particle.	Control particles 0.1% (w / w) NOTE: This product contain Latex particle.				
	prepared from human urine;					
MEDITAPE CHECK 1	Chemical and biochemical substances as well as constituents of human origin are contained.					
	prepared from human urine;	prepared from human urine;				
MEDITAPE CHECK 2	Chemical and biochemical substances as well as constituents of human origin are contained.					
	Control particles 0.4% (w / w)					
UF II Calibrator	NOTE : This product contain Latex particle.					

On behalf of Sysmex Europe GmbH

i.A. Katharina Paucke

Manager Regulatory Affairs

Date: January 19th, 2016

Place: 22848 Norderstedt, Germany

Sysmex Europe GmbH Bornbarch 1 22848 Norderstedt

"Design and specifications may be subject to changes due to further product development. Changes are confirmed by the reached on a newer document and verification according to its date of issue."



Application of Counc	il Directive:
98/79/EC of 27 Octob	er 1998 on In Vitro Diagnostic Medical Devices
Means of conformity:	*
	is in conformity with Directive 98/79/EC based on the conformity in accordance with Annex III of the Directive.
Product identification	:
Product name:	CELLPACK DCL
Classification:	Other device (except Annex II and self-testing devices)
Authorised represent	
Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	Kohei Sumitani, Managing Director
Legal Manufacturer:	
Name:	SYSMEX CORPORATION
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
Authorised officer:	Keiji Fujimoto, Executive Officer Date: Jan. 23, 2014
	SOCIETATES OF THE STATE OF THE

Sysmex Corporation

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



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: Lysercell WNR Classification: Other device (except Annex II and self-testing devices) Authorised representative: Name: SYSMEX EUROPE GMBH Address: Bornbarch 1, 22848 Norderstedt, Germany Date: 31.1.0014 Authorised officer: Kohei Sumitani, Managing Director Legal Manufacturer: Name: SYSMEX CORPORATION 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan Address: Authorised officer: Date: Jan. 23, 2014 Keiji Fujimoto, Executive Officer

Sysmex Corporation

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

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EC Declaration of Conformity

Application of Counc	il Directive:
98/79/EC of 27 Octob	er 1998 on In Vitro Diagnostic Medical Devices
Means of conformity:	
	t is in conformity with Directive 98/79/EC based on the conformity in accordance with Annex III of the Directive.
	440
Product identification	
Product name:	Lysercell WDF
Classification:	Other device (except Annex II and self-testing devices)
Authorised represent	ative:
Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	lykei Sum 1 Date: 37.1.2004
	Kohei Sumitani, Managing Director
Legal Manufacturer:	
Name:	SYSMEX CORPORATION
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
Authorised officer:	M. June Date: Jan. 23, 2014
, idiliolidad ollidoli	Keiji ujimoto, Executive Officer
	WAU. SOCIETA

Sysmex Corporation

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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.

Prod	LICT	ida	ntifi	cat	ion
1100	uct	luc	111111	cai	1011.

Product name:

Fluorocell WNR

Classification:

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

Authorised representative:

Name:

SYSMEX EUROPE @MBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Date: DEC. 114, 7017

Fernando Apereu, Chief Operations Officer

Legal Manufacturer:

Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

___ Date.

Date: Nov 20, 2017

Hiroshi Yamane, Executive Vice President





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.

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Prod	LICT	10	ant	ITICS	ation	١.
1 100	uci	IU	CIT	11100		ι.

Product name:

Fluorocell WDF

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:

DEC 114, 2017

Fernando Andreu, Chief Operations Officer

Legal Manufacturer:

Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Hiroshi Yamane, Executive Vice President





Application of Counci	I Directive:
98/79/EC of 27 Octob	er 1998 on In Vitro Diagnostic Medical Devices
Means of conformity:	
0.1	is in conformity with Directive 98/79/EC based on the conformity in accordance with Annex III of the Directive.
Product identification	
Product name:	SULFOLYSER
Classification:	Other device (except Annex II and self-testing devices)
Authorised represent	ative:
Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	Kohei Sumitani, Managing Director
	Koner Summan, Managing Director
Legal Manufacturer:	
Name:	SYSMEX CORPORATION
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
Authorised officer:	Keiji Fajimoto, Executive Officer Date: Jan. 23, 2014
	AND SERVICE AND PROPERTY OF THE PROPERTY OF TH

Sysmex Corporation

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

Tel. +81-78-265-0500 Fax. +81-78-265-0524



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EC Declaration of Conformity

Application of Counci	Directive:
98/79/EC of 27 Octobe	er 1998 on In Vitro Diagnostic Medical Devices
Means of conformity:	
	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:	
Classification:	Other device (except Annex II and self-testing devices)
Classification.	Other device (except runies if and seri testing devices)
Authorised represent	ative:
Name:	SYSMEX EUROPE GMBH
Address:	Bornbarch 1, 22848 Norderstedt, Germany
	Who Sunt Date: 31. 1. 2014
Authorised officer:	Kohei Sumitani, Managing Director
	Teorier Summany Managers 2 months
Legal Manufacturer:	CYCLUTY CORROR ATION
Name:	SYSMEX CORPORATION 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
Address:	1-3-1 Wakinonama-Kaigandon, Chuo-ku, Rooc 031-0073 Japan
Authorised officer:	Date: Jan. 23, 2014
	Keiji Enimoro, Executive Officer
	and the second s

Sysmex Corporation

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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	Ider	ntitica	ation:
1 100000	IUU	ILIIIO	ationis

Product name:

XN CAL

Classification:

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

Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

DEC 11th , 2017 Date:

Fernando Andreu, Chief Operations Officer

Legal Manufacturer:

Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Hiroshi Yamane, Executive Vice President

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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

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Prod	LICT	100	antit	100	tio	n'
1 100	uct	100	JI I (100	LIU	11.

Product name:

XN CHECK

Classification:

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

Authorised representative:

Name:

SYSMEX EUROPE GMBH

Address:

22848 Norderstedt, Germany Børnbarch V.

Authorised officer:

Date: Fernando Andreu, Chief Operations Officer

DEC 11th, 2017

Legal Manufacturer:

Name:

SYSMEX CORPORATION

Address:

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

Authorised officer:

Hiroshi Yamane, Executive Vice President

www.sysmex.co.jp