

Sysmex Europe GmbH · Bornbarch 1 · 22848 Norderstedt · Germany

To whom it may concern

Sysmex Europe GmbH
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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.

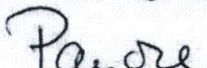
Therefore Sysmex Reagents offer best performance on Sysmex Analysers.

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
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 Völkel

The Bank of Tokyo-Mitsubishi UFJ, Ltd. Hamburg
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IBAN DE03 3001 0700 0000 0377 13
SWIFT/BIC Code BOTKDE33

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Composition of Sysmex Reagents

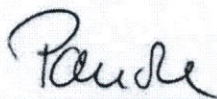
The composition of Sysmex Reagents is highly confidential! Therefore only active components and those classified as dangerous must be declared on the package label.

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>DILUENT (BLUE)</td><td>LYSING REAGENT (PURPLE)</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>	DILUENT (BLUE)	LYSING REAGENT (PURPLE)	• 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	
DILUENT (BLUE)	LYSING REAGENT (PURPLE)										
• 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											
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



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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:

Kohei Sumitani
Kohei Sumitani, Managing Director

Date: 31. 7. 2014

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

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:

Kohei Sumitani
Kohei Sumitani, Managing Director

Date: 31.7.2014

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



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

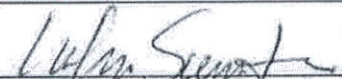
Classification: Other device (except Annex II and self-testing devices)

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:


Kohei Sumitani, Managing Director

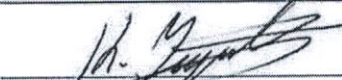
Date: 31. 1. 2014

Legal Manufacturer:

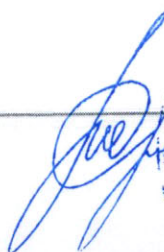
Name: SYSMEX CORPORATION

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

Authorised officer:


Keiji Fujimoto, Executive Officer

Date: Jan. 23, 2014



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
Takeshi Kubota, Managing Director

Date: 10. Aug. 2015

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: Hiroshi Yamane
Hiroshi Yamane, Executive Vice President

Date: 14 July, 2015

