

Product identification:	CELL BACK DOL			
Product name:	CELLPACK DCL			
Model name: REF code:	N/A CT-661-628, CU-228-496			
BUDI-DI:	4987562CELLPACKDCLX9			
	See attachment			
Intended Purpose	See attachment			
Manufacturer: Name:	SYSMEX CORPORATION			
Single Registration Number:	JP-MF-000014037			
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan			
Authorised representative: Name:	SYSMEX EUROPE SE			
Single Registration Number:	DE-AR-000022333			
Address:	Bornbarch 1, 22848 Norderstedt, Germany			
SYSMEX CORPORATION, as hereby declare that the above	s the manufacturer of the device, take sole responsibility for and mentioned device meets the provisions of the following Regulation:			
	on In vitro Diagnostic Medical Devices ective(s) as applicable for the device(s):			
Risk class: ☑ A □ B □	, o D			
Conformity route: Annex I+II+III according to Art	icle 48 (10) of EU 2017/746			
Common Specification: N/A				
Takashi Demachi Executive Vice President	Name Place Date (DD.MM.YYYY)			

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Page 1 of 2



Product identification:				
Product name:	SULFOLYSER			
Model name:	N/A			
REF code:	054-3351-4, 904-1131-7, AS788212, 904-1141-4			
BUDI-DI:	4987562SULFOLYS	ERBV		
Intended Purpose	See attachment			
Manufacturer:				
Name:	SYSMEX CORPORA	ATION		
Single Registration Number:	JP-MF-000014037			
Address:	1-5-1 Wakinohama-l	Kaigandori, Chuo-ku, I	Kobe 651-0073 Japan	
Authorised representative:				
Name:	SYSMEX EUROPE	SE		
Single Registration Number:	DE-AR-000022333			
Address:	Bornbarch 1, 22848 Norderstedt, Germany			
SYSMEX CORPORATION, as the manufacturer of the device, take sole responsibility for and hereby declare that the above mentioned device meets the provisions of the following Regulation:				
Regulation EU 2017/746 on <i>In vitro</i> Diagnostic Medical Devices Other Regulation(s)/Directive(s) as applicable for the device(s):				
Risk class: ☑ A □ B □	, C 🗆 D			
Conformity route: Annex I+II+III according to Arti	cle 48 (10) of EU 201	7/746		
Common Specification: N/A				
Tokar L. Dunde	Z ko	be Tapan	21/04/2022	
Takashi Demachi Executive Vice President	Name Pl. Function	ace	Date (DD.MM.YYYY)	

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Page 1 of 2



Product identification: Product name:	Lysercell WDF			
Model name:	N/A			
REF code:	AL-337-564, BG-689-680, AZ-124-801, AW-993-605			
BUDI-DI:	4987562LysercellWDFXJ			
Intended Purpose	See attachment			
Manufacturer: Name:	SYSMEX CORPORATION			
Single Registration Number:	JP-MF-000014037			
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku,	Kobe 651-0073 Japan		
Authorised representative: Name: Single Registration	SYSMEX EUROPE SE			
Number:	DE-AR-000022333			
Address:	Bornbarch 1, 22848 Norderstedt, Germany			
hereby declare that the above	the manufacturer of the device, take sole mentioned device meets the provisions of on <i>In vitro</i> Diagnostic Medical Devices			
☐ Other Regulation(s)/Dire	ctive(s) as applicable for the device(s):			
Risk class: ☑ A □ B □	, C D			
Conformity route: Annex I+II+III according to Art	icle 48 (10) of EU 2017/746			
Common Specification: N/A				
Twicas L. Dence Takashi Demachi Executive Vice President	Name Place Function	Date (DD.MM.YYYY)		

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Page 1 of 2



Product identification:				
Product name:	Fluorocell WDF			
Model name:	N/A			
REF code:	AE687941, BY458697, BJ284784, CV-37	7-552, AA-325-279		
BUDI-DI:	4987562FLUOROCELLWDFWE			
Intended Purpose	See attachment			
Manufacturer:				
Name:	SYSMEX CORPORATION			
Single Registration Number:	JP-MF-000014037			
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku,	Kobe 651-0073 Japan		
Authorised representative:	SYSMEX EUROPE SE			
Single Registration	DE-AR-000022333	2 29		
Number:	Manual Annual			
Address:	Bornbarch 1, 22848 Norderstedt, Germany			
	s the manufacturer of the device, take sole mentioned device meets the provisions of			
	on <i>In vitro</i> Diagnostic Medical Devices ective(s) as applicable for the device(s):			
Risk class: ☑ A □ B □	, C D			
Conformity route: Annex I+II+III according to Art	icle 48 (10) of EU 2017/746			
Common Specification: N/A				
		* *		
Takenst Depart	n. kope Japan	25/05/2022		
Takashi Demachi	Name Place	Date		
Executive Vice President	Function	(DD.MM.YYYY)		
		Later an		

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Product identification: Product name:	CELLCLEAN			
Model name:	N/A			
REF code:	834-0162-1, BU037001			
BUDI-DI:	4987562CELLCI	_EANP7	-	
Intended Purpose	See attachment			
Manufacturer:				
Name:	SYSMEX CORP	ORATION		
Single Registration Number:	JP-MF-00001403	37		
Address:	1-5-1 Wakinohar	ma-Kaigandori, Ch	uo-ku, Kobe 651-0073 Japan	
Authorised representative: Name:	SYSMEX EURO	PE SE		
Single Registration Number:	DE-AR-0000223	33		
Address:	Bornbarch 1, 228	348 Norderstedt, G	Germany	
 ✓ Regulation EU 2017/746 ✓ Other Regulation(s)/Direction Risk class: ✓ A 	_	able for the device(
Conformity route: Annex I+II+III according to Ar		2017/746		
Common Specification: N/A				
Taxas L. Depu	al.	Kobe Japan	25/05/2022	
Takashi Demachi Executive Vice President	Name Function	Place	Date (DD.MM.YYYY)	
		Media	SOCIETATES OF PUNDERS	

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Application	of	Council	Directive:
Application	OI	Council	Directive.

_	98/79/EC of 27	October	1998 on In	Vitro	Diagnostic	Medical	Devices.
-	70/ / 7/ EC 01 2 /	October	1 2 2 0 0 11 111	VILIO	Diagnostic	Miculcai	DUVICUS.

Means of conformity:

The following products are in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III.

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г	IUU	uct	lue	Hun	ual	IUI	

Product name:

XN-L CHECK

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:

Takashi Demachi, Executive Vice President

Authorised representative:

Name:

SYSMEX EUROPE SE

Address:

Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

Sinem Yaman, Vice President, Head of Regulatory Affairs,

Quality Assurance, Quality Control

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until the end of transitional period stipulated in REGULATION (EU) 2017/746 & its related regulations. The Classification of this product under REGULATION (EU) 2017/746 is Class B.

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Application of Council - 98/79/EC of 27 Octo	Directive: ber 1998 on In Vitro Diagnostic Medical Devices.
	s are in conformity with assed on the conformity assessment procedures in accordance with
Product identification: Product name:	XN CAL
Classification:	Other device (except Annex II and self-testing devices)
List of Applied Standard	rds: Is used for conformity assessment are listed in the technical
documentation.	is used for comornity assessment are fisted in the technical
Legal Manufacturer:	SYSMEX CORPORATION
Address:	1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
Authorised officer:	Takashi Demachi, Executive Vice President
Authorised representa	tive:
Name:	SYSMEX EUROPE SE
Address:	Bornbarch 1, 22848 Norderstedt, Germany
Authorised officer:	Sinem Yaman, Vice President, Head of Regulatory Affairs,
	Quality Assurance, Quality Control

This declaration of conformity is issued under the sole responsibility of the manufacture and the end of transitional period stipulated in REGULATION (EU) 2017/746 & its related regular Classification of this product under REGULATION (EU) 2017/746 is Class By