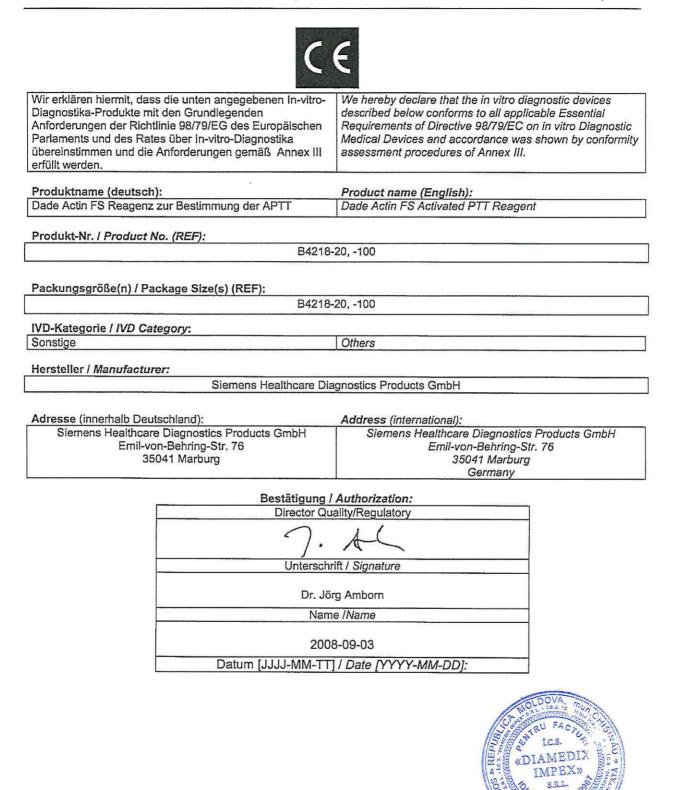
Declaration of Conformity

	C	E	
Wir erklären hiermit, dass die unter		We hereby declare that the in vitro diagno.	stic devices
Diagnostika-Produkte mit den Grur		described below conforms to all applicable	
Anforderungen der Richtlinie 98/79		Requirements of Directive 98/79/EC on in	vitro Diagnostic
Parlaments und des Rates über In-		Medical Devices and accordance was sho	wn by conformity
übereinstimmen und die Anforderu erfüllt werden.	ngen gemais Annex III	assessment procedures of Annex III.	
endit werden.	C.	I	
Produktname (deutsch):		Product name (English):	
Thromborel S		Thromborel S	
Produkt-Nr. / Product No. (REF):			
	OL	JHP	
Packungsgröße(n) / Package Siz	e(s) (REF):		180
		, OUHP 49	
IVD-Kategorie / IVD Category:		0/	
Sonstige		Others	
Hersteller / Manufacturer:			
	Siemens Healthcare Dia	gnostics Products GmbH	
			anne i ann an
Adresse (innerhalb Deutschland):			
Siemens Healthcare Diagnost	ice Producte CmbU	Address (international):	duala Cashili
Emil-von-Behring		Siemens Healthcare Diagnostics Pro Emil-von-Behring-Str. 76	
35041 Marbu		35041 Marburg	
00041 Marba	19	Germany	
		Connuny	
		Authorization:	
	Director Qu	ality/Regulatory	
	7.	A	
Unterschrift / Signature			
	Onterson		
	Dr. Jör	rg Amborn	
	Nam	e IName	A. m
		N. C. L. TO	S. DIL NEON
	2008	8-09-03	FACT
	Datum [JJJJ-MM-TT]	I Date [YYYY-MM-DD]:	s. The state
F		UVID NO VICE A REP	MEDIA PEX» SAL 126000
		CD	RAST

Konformitätserklärung

Declaration of Conformity





Siemens Healthcare Diagnostics Products GmbH

Konformitätserklärung

Declaration of Conformity



Wir erklären hiermit, dass die unten angegebenen In-vitro- Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III	We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.
erfüllt werden.	assessment procedures of Annex III.
Produktname (deutsch):	Product name (English):
Calciumchlorid-Lösung	Calcium Chloride Solution
Produkt-Nr. / Product No. (REF):	
	RHO
Packungsgröße(n) / Package Size(s) (REF):	
ORI	HO 37
IVD-Kategorie / IVD Category:	
Sonstige	Others
Hersteller / Manufacturer:	
Siemens Healthcare Dia	agnostics Products GmbH
Adresse (innerhalb Deutschland):	Address (international):
Siemens Healthcare Diagnostics Products GmbH	Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76 35041 Marburg	Emil-von-Behring-Str. 76
SS04 I Marburg	35041 Marburg Germany
Bestätigung /	/ Authorization: Jality/Regulatory
Untersch	rift / Signature
	rg Amborn
Nam	ne /Name
2009-11-05	
Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:	
	<u>11040 [1111 WW 00].</u>
	CUSTANU FACTO MIRU FACTO MILOS MIRU FACTO MILOS MILOS MILOS S.R.L

LP-00101_VL_DoC - Gültig ab: 2009-06-08

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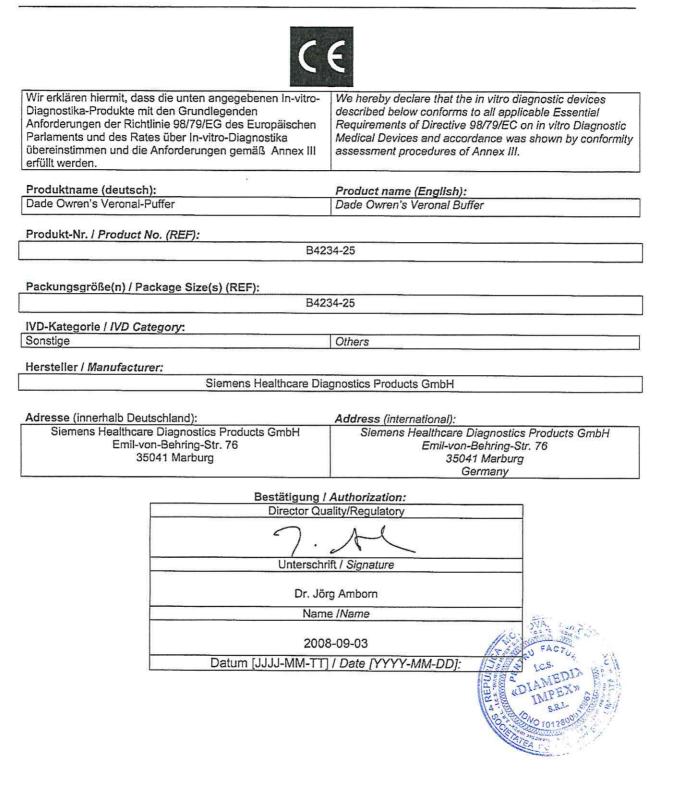
Vertrauliche Informationen von Siemens Healthcare Diagnostics / Proprietary Information of Siemens Healthcare Diagnostics

Konformitätserklärung Declaration of Conformity



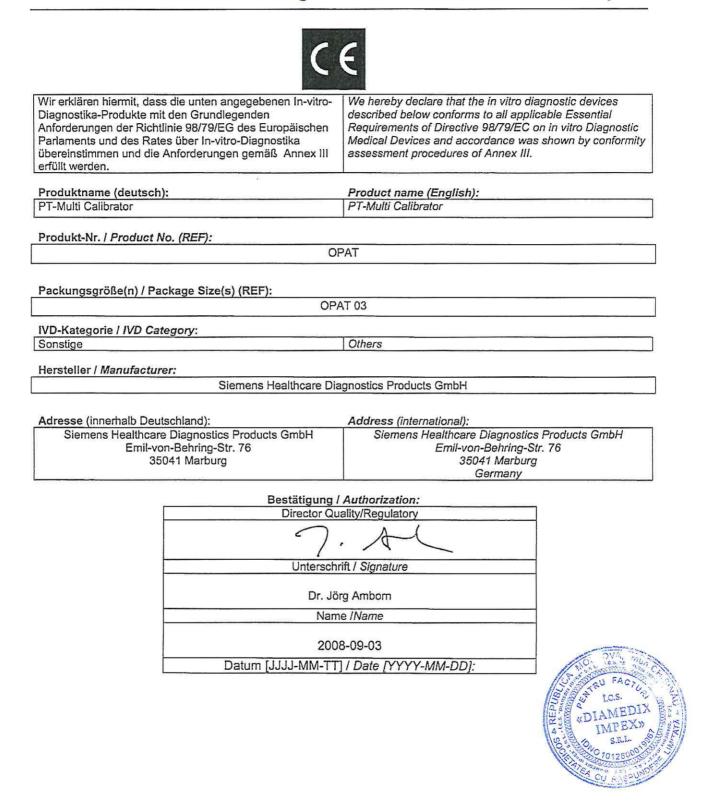
C	E	
Wir erklären hiermit, dass die unten angegebenen In-vitro- Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III erfüllt werden.	We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.	
Produktname (deutsch):	Product name (English):	
Dade Thrombin Reagenz	Dade Thrombin Reagent	
Produkt-Nr. / Product No. (REF):		
	3-25, -27	
است. المعالية		
Packungsgröße(n) / Package Size(s) (REF):		
	-25, -27	
IVD-Kategorie / IVD Category:		
Sonstige	Others	
Hersteller / Manufacturer:	Street Street	
	agnostics Products GmbH	
Adresse (innerhalb Deutschland):	Address (international):	
Siemens Healthcare Diagnostics Products GmbH	Siemens Healthcare Diagnostics Products GmbH	
Emil-von-Behring-Str. 76 35041 Marburg	Emil-von-Behring-Str. 76 35041 Marburg	
	Germany	
Director Qui	Authorization: ality/Regulatory	
\mathcal{I}	· A	
Unterschr	ift / Signature	
Dr. Jör	g Amborn	
Name	e IName	
2008	3-09-03	
Datum [JJJJ-MM-TT]	I Date [YYYY-MM-DD]:	
	TDate [YYYY-MM-DD]: TDate [YYYY-MM-DD]: TO ALL CS THE BLY SILE OVO 101280000000000000000000000000000000000	
	ATEA CU RIS	

Declaration of Conformity



Konformitätserklärung / Declaration of Conformity (DoC)

Declaration of Conformity



Konformitätserklärung

Declaration of Conformity



Wir erklären hiermit, dass die unten angegebenen In-vitro- Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III	We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.	
erfüllt werden. Produktname (deutsch):	Product name (English):	
Standard-Human-Plasma	Standard Human Plasma	

Produkt-Nr. / Product No. (REF):

ORKL

Packungsgröße(n) / Package Size(s) (REF)

ORKL 13, ORKL 17, ORKL 21

IVD-Kategorie / IVD Category: Sonstige

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Others

resse (innerhalb Deutschland):	Address (international);
Siemens Healthcare Diagnostics Products GmbH	Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76	Emil-von-Behring-Str. 76
35041 Marburg	35041 Marburg
2 S S 🖉	Germany

Bestätigung / Authorization: Director Quality/Regulatory N. Unterschrift / Signature Dr. Wilhelm Schuy Name /Name 2009-08-05 Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:

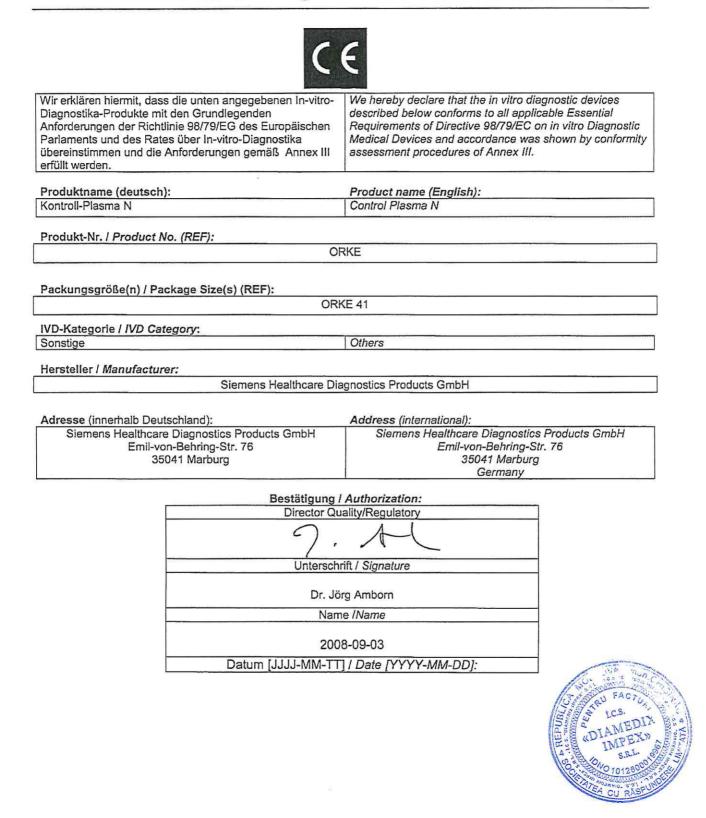


LP-00101_VL_DoC - Gültig ab: 2009-06-08

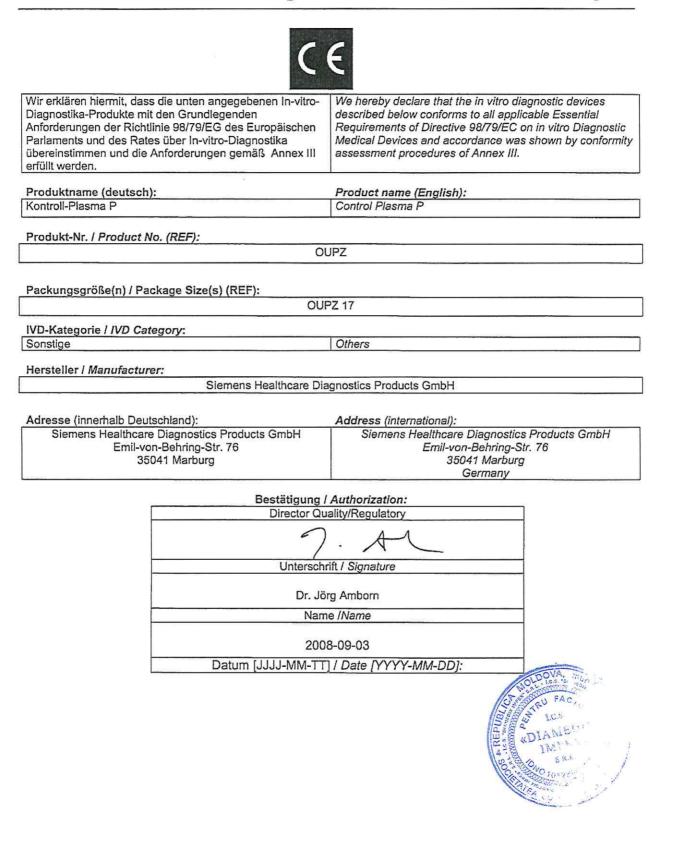
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Vertrauliche Informationen von Siemens Healthcare Diagnostics / Proprietary Information of Siemens Healthcare Diagnostics

Declaration of Conformity



Declaration of Conformity



Konformitätserklärung / Declaration of Conformity (DoC)

Konformitätserklärung

Declaration of Conformity

	C	ε	
Anforderungen der Rich Parlaments und des Ra	ss die unten angegebenen In-vitro- nit den Grundlegenden tillinle 98/79/EG des Europäischen tes über In-vitro-Diagnostika Anforderungen gemäß Annex III	We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.	
Produktname (deutsch	Produktname (deutsch): Product name (English):		
Dade CI-Trol 2		Dade Ci-Trol 2	
Produkt-Nr. / Product	Produkt-Nr. / Product No. (REF):		
291071			
Packungsgröße(n) / Pa	Packungsgröße(n) / Package Size(s) (REF):		
IVD-Kategorie / IVD Ca	291	0/1	
Sonslige	tegory:	Olhers	
Hersteller / Manufactur		<u>Olhers</u>	
Therstener / Wanufactur			
	Slemens Healthcare Dia	anostics Products GmbH	
Siemens Healthcar	Adresse (Innerhalb Deutschland): Address (International): Siemens Healthcare Diagnostics Products GmbH Siemens Healthcare Diagnostics Products GmbH		
Cmil-vo	Emil-von-Behring-Str. 76 35041 Marburg Germany		
	Bestätigung / ,	Authorization:	
	Director Qua	lity/Regulatory	
	7.1		
	Unterschrif	t / Signature	
.3	Dr. Jörg	Amborn	
	Name	IName	
		-09-03	
3	Datum [JJJJ-MM-TT]	Dale [YYYY-MM-DD]:	
Konformitätserkläning		USA MURO USA MURO USA MURO USA LCS. USA LCS. UDIAMEDIA UDIAMEDIA SIL SIL SIL CURASPUT	
I Konformitätserklärung /	Declaration of Conformity (DoC)	Colle / De	
Digitally signed by Marinescu Traian Alin Date: 2019.11.04 08:57:48 EET Reason: MoldSign Signature Location: Moldova		Seite / Page: 1 von / of 1	



SYSMEX CORPORATION

Mail to 1:1-5-1 Wakinon4ma-Kaigandon, Chuo-ku, Kobe 651-0073, Japan Phone 1:81-76-265-0590 Faosimile 1:81-76-265-0524

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 test results using harmonised standards in accordance with Article 5 of the Directive.

Product identification:

Product name: CA CLEAN II

Manufacturer:

Name: SYSMEX CORPORATION

Address: <u>1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073</u> Country: Japan

Authorised representative:

Name:	SYSMEX EUROPE GMBH	
Address:	Bornbarch 1, 22848 Norderstedt	
Country:	Germany	
Authorised officer:	Iwane Matsui	
Position:	President	
Date:	9TH TANUARY 2002	
Place:	NOLDELSTEDT GERMANY	
This certificate was issue	ed under sole responsibility of:	
Authorised officer:	- that	
	Tokuhiro Okada	Constant and
	Vice President, Technology Control	(2) = (1) =
Date:	november 7, 200/	
Place:	Japan	13180 and the Ast
		No. 2000 19 19



SYSMEX CORPORATION

Mail to 1-5-1 Wakinonama-Kaigandori,Chue-ku,Kobe 651-0073,Japar Phone 61-75-25-0500 Fassimile 121-78-25-0524

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 test results using harmonised standards in accordance with Article 5 of the Directive.

Product identification:

Product name: CA CLEAN I

Manufacturer:

 Name:
 SYSMEX CORPORATION

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

 Country:
 Japan

Authorised representative:

 Name:
 SYSMEX EUROPE GMBH

 Address:
 Bornbarch 1, 22848 Norderstedt

Country: Germany

Authorised officer:

Iwane Matsui

Position: President

Date: 9TH JANUARY 2002 Place: NOTDERSTEPT, GERMAN

This certificate was issued under sole responsibility of:

Authorised officer:	- AM	
	Tokuhiro Okada	NOLUOVA: TUR
Position:	Vice President, Technology Control	CLASSEN FACT
Date:	november 7, 200/	A LCS.
Place:	Japan	IMPEX» APIE
		000 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
		CU RASPUNO



SYSMEX CORPORATION

Mail to 11-5-1 Wakinchama-Kaigandori Chuc-ku Kobe 651-0073.Jaoan Phone 181-78-265-0500 Facsimile 181-78-265-0524

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 test results using harmonised standards in accordance with Article 5 of the Directive.

Product identification:

Product: <u>REACTION TUBE</u> Model: <u>SU-40</u>

Manufacturer:

 Name:
 SYSMEX CORPORATION

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

 Country:
 Japan

Authorised representative:

	2. 		
	Name:	SYSMEX EUROPE GMBH	
	Address:	Bornbarch 1, 22848 Norderstedt	
	Country:	Germany	
	Authorised officer:	Iwane Matsui	
	Position:		
	Date:	10TH JANUARY 2002	
	Place:	NORAFLISTEDT, GERMANY	0014
د	This certificate was issue	ر ed under sole responsibility of:	The RUFACTURE
	Authorised officer: -	Tokuhiro Okada	COLONIA SEL
		Vice President, Technology Control	10126000
	Date:	november 16, 200/	C RASPO
	Place:	Japan	