

# SIEMENS

## 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 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):

Thromborel S

Product name (English):

Thromborel S

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

OUHP

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

OUHP 29, OUHP 49

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

7. KS

Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2008-09-03

Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:



# Sysmex

SYSMEX CORPORATION

Kodok  
1-5-1 Wakunagomachi-Kuigandori, Chuo-ku, Kobe 651-0073, Japan  
Phone : 81-78-265-0500  
Fax : 81-78-265-0524

## 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 name: CA CLEAN I

Manufacturer:

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakunagomachi-Kuigandori, Chuo-ku, Kobe 651-0073

Country: Japan

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarth 1, 22848 Norderstedt

Country: Germany

Authorised officer:

Iwane Matsui

Position: President

Date: 9TH JANUARY 2002

Place: NORDERSTEDT, GERMANY

This certificate was issued under sole responsibility of:

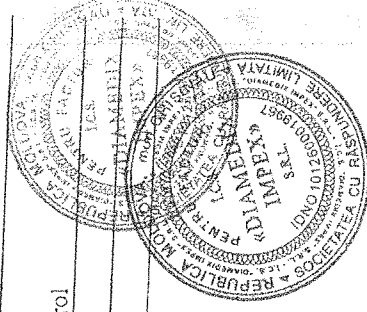
Authorised officer:

Tokuhiro Okada

Position: Vice President, Technology Control

Date: November 7, 2001

Place: Japan



# Sysmex

SYSMEX CORPORATION

1-5-1 Wakoinohama, Nakagyo-ku, Kyoto 605-0073, Japan  
Tel: 81-75-285-5350  
Fax: 81-75-285-5354

## 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: 1-5-1 Wakoinohama-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: NORDERSTEDT GERMANY

This certificate was issued under sole responsibility of:

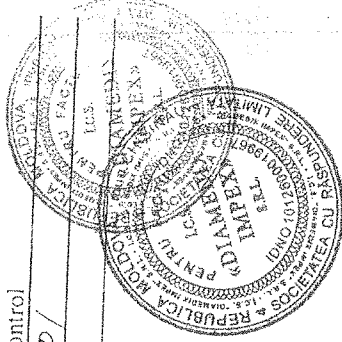
Authorised officer:

  
Tokuhiko Okada

Position: Vice President, Technology Control

Date: November 7, 2001

Place: Japan



# SIEMENS

## 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 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):

Dade Actin FS Reagenz zur Bestimmung der APTT

### Product name (English):

Dade Actin FS Activated PTT Reagent

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

B4218-20, -100

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

B4218-20, -100

### IVD-Kategorie / IVD Category:

Sonstige

Others

### Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

### Adresse (Innereib Deutschland):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

### Address (International):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

### Bestätigung / Authorization:

Director Quality/Regulatory

J. AL

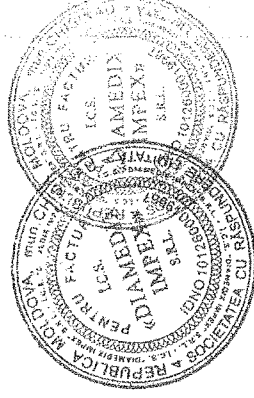
Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



Konformitätserklärung / Declaration of Conformity (DoC)

Seite / Page: 1 von / of 1

# SIEMENS

## 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 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):  
Dade Thrombin Reagenz

Product name (English):  
Dade Thrombin Reagent

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

B4233-25, -27

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

B4233-25, -27

IVD-Kategorie / IVD Category:  
Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Bestätigung / Authorization:  
Director Quality/Regulatory

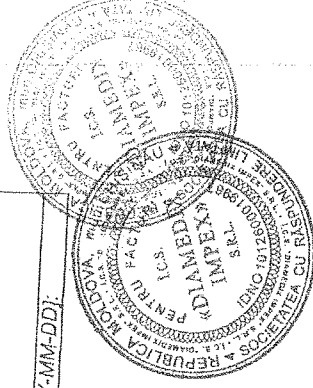
Unterschrift / Signature

Dr. Jörg Ansbom

Name / Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



# SIEMENS

## 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 II 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):

Dade Owren's Veronal-Puffer

Product name (English):

Dade Owren's Veronal Buffer

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

B4234-25

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

B4234-25

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

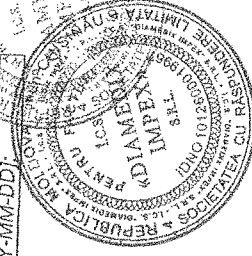
Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2008-09-03

Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:



Konformitätserklärung / Declaration of Conformity (DoC)

Seite / Page: 1 von / of 1

# SIEMENS

## 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 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):  
INNOVANCE D-Dimer

Product name (English):  
INNOVANCE D-Dimer

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

OPBP

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

OPBP 03, OPBP 07

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

Address (International):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

7. AS

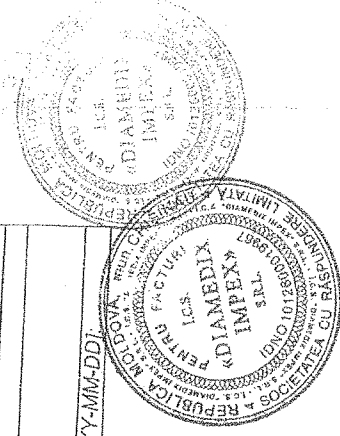
Unterschrift / Signature

Dr. Jörg Amborn

Name /Name

2008-09-03

Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]



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## 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 erfüllt werden.

We hereby declare that the in vitro diagnostic devices described below conform 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):  
Test-Thrombin-Reagenz

Product name (English):  
Test Thrombin Reagent

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

OWHM

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

OWHM 13

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Bestätigung / Authorization:  
Director Quality/Regulatory

7. AS

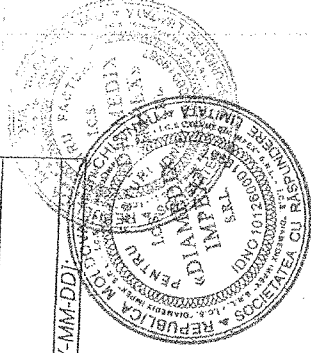
Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



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## 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 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):

Kontroll-Plasma N

Product name (English):

Control Plasma N

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

ORKE

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

ORKE 41

IVD-Kategorie / IVD Category:

Sonstige

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

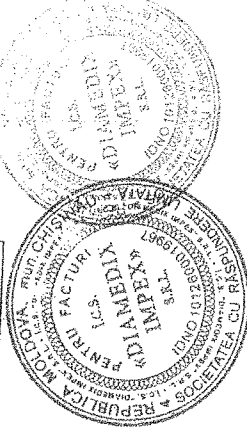
Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



# SIEMENS

## 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 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):

Kontroll-Plasma P

Product name (English):

Control Plasma P

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

OUPZ

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

OUPZ 17

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (Innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

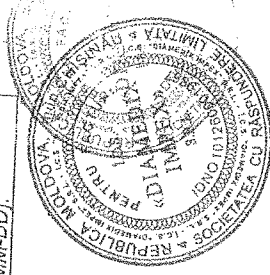
Unterschrift / Signature

Dr. Jörg Amborn

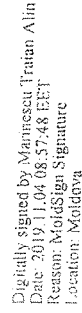
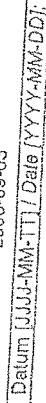
Name /Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



### Declaration of Conformity



# SIEMENS

## 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 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):

INNOVANCE D-Dimer Controls

Product name (English):

INNOVANCE D-Dimer Controls

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

OPDY

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

OPDY 03

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (Innereilb Deutschland):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

Address (International):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

*J. M.*

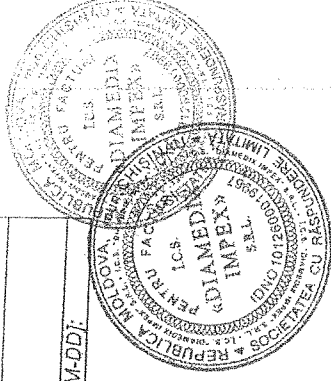
Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2008-09-03

Datum [JJJJ-MM-TT] / Date [YYYY-MM-DD]:



# SIEMENS

## 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 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):

PT-Multi Calibrator

Product name (English):

PT-Multi Calibrator

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

OPAT

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

OPAT 03

IVD-Kategorie / IVD Category:

Sonstige

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Bestätigung / Authorization:

Director Quality/Regulatory

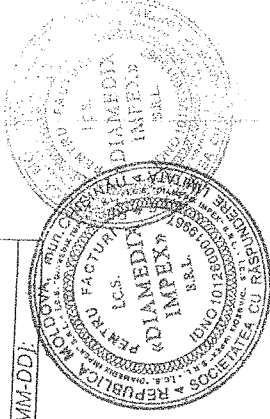
Unterschrift / Signature

Dr. Jörg Amborn

Name / Name

2008-09-03

Datum (JJJJ-MM-TT) / Date (YYYY-MM-DD):



Konformitätserklärung / Declaration of Conformity (DoC)

Seite / Page: 1 von / of 1

## 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 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):

Standard-Human-Plasma

Product name (English):

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

Others

Hersteller / Manufacturer:

Siemens Healthcare Diagnostics Products GmbH

Adresse (Innerhalb Deutschlands):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg

Address (International):

Siemens Healthcare Diagnostics Products GmbH  
Emil-von-Behring-Str. 76  
35041 Marburg  
Germany

Bestätigung / Authorization:  
Director Quality/Regulatory

*W. Schuy*

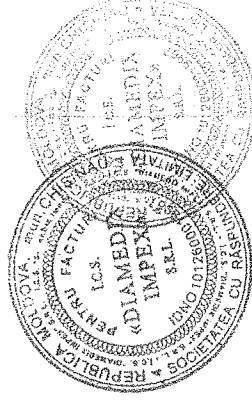
Unterschrift / Signature

Dr. Wilhelm Schuy

Name / Name

2009-08-05

Datum [JJJ-MM-TT] / Date [YYYY-MM-DD]:



**sysmex**

SYSMEX CORPORATION

Mak. to : I.E.S. Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan  
Phone : 81-78-265-0000  
Fax : 81-78-265-0024

# 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: REACTION TUBE

Model: SU-40

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: 10TH JANUARY 2002

Place: NORDERSTEDT, GERMANY

This certificate was issued under sole responsibility of:

Authorised officer:

Tokuhiro Okada

Position: Vice President, Technology Control

Date: November 16, 2001

Place: Japan

