SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):*
Thromborel S	*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):	*Address (international):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*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*

CE

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 Actin FS Reagenz zur Bestimmung der APTT	*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 (innerhalb Deutschland):	*Address (International):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*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

Siemens Healthcare Diagnostics
Products GmbH

Konformitätserklärung

Declaration of Conformity

CE

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):*
Calciumchlorid-Lösung	*Calcium Chloride Solution*

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

ORHO

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

ORHO 37

IVD-Kategorie / *IVD Category:*

Sonstige	*Others*

Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	*Address (international):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*Siemens Healthcare Diagnostics Products GmbH* *Emil-von-Behring-Str. 76* *35041 Marburg* *Germany*

Bestätigung / *Authorization:*

Director Quality/Regulatory
Unterschrift / *Signature*
Dr. Jörg Ambom
Name /*Name*
2009-11-05
Datum [JJJJ-MM-TT] / *Date [YYYY-MM-DD]:*

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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)*:

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):	*Address (international)*:
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*Siemens Healthcare Diagnostics Products GmbH* *Emil-von-Behring-Str. 76* *35041 Marburg* *Germany*

Bestätigung / *Authorization*:

Director Quality/Regulatory

Unterschrift / *Signature*

Dr. Jörg Ambom

Name /*Name*

2008-09-03

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

REPUBLICA MOLDOVA I.C.S. «DIAMED-IMPEX» S.R.L. IDNO 1012600019986 SOCIETATEA CU RĂSPUNDERE LIMITATĂ PENTRU FACTURI

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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 Owren's Veronal-Puffer	*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):	*Address (international):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*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*

CE

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):*
INNOVANCE D-Dimer	*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):	*Address (International):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*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]*

REPUBLICA MOLDOVA PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019087 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):*
INNOVANCE D-Dimer Controls	*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 (innerhalb Deutschland):	*Address (International):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*Siemens Healthcare Diagnostics Products GmbH* *Emil-von-Behring-Str. 76* *35041 Marburg* *Germany*

Bestätigung / *Authorization:*

Director Quality/Regulatory
7. M
Unterschrift / *Signature*
Dr. Jörg Amborn
Name /*Name*
2008-09-03
Datum [JJJJ-MM-TT] / *Date [YYYY-MM-DD]:*

REPUBLICA MOLDOVA, I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019567 SOCIETATEA CU RĂSPUNDERE LIMITATĂ PENTRU FACTURA

Sysmex SYSMEX CORPORATION
Mail to : 1-5-1 Wakinohama-Kaigandori, Chuo-ku Kobe 651-0073 Japan
Phone : 81-78-265-0500
Facsimile : 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 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: 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

REPUBLICA MOLDOVA «DIAMED IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RASPUNDERE LIMITATA

Sysmex SYSMEX CORPORATION

Mail to : 1-5-1 Wakinohama-Kaigandori,Chuo-ku,Kobe 651-0073,Japan
Phone : 81-78-265-0500
Facsimile : 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 II

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: 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

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):*
PT-Multi Calibrator	*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):	*Address (international):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*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]:*

REPUBLICA MOLDOVA, mun. CHIŞINĂU, PENTRU FACTURĂ, I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019864, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

Siemens Healthcare Diagnostics
Products GmbH

Konformitätserklärung

Declaration of Conformity

CE

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):*
Standard-Human-Plasma	*Standard Human Plasma*

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

ORKL

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

ORKL 13, ORKL 17, ORKL 21

IVD-Kategorie / *IVD Category:*	
Sonstige	*Others*

Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	*Address (International):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*Siemens Healthcare Diagnostics Products GmbH* *Emil-von-Behring-Str. 76* *35041 Marburg* *Germany*

Bestätigung / *Authorization:*

Director Quality/Regulatory

W. Schuy

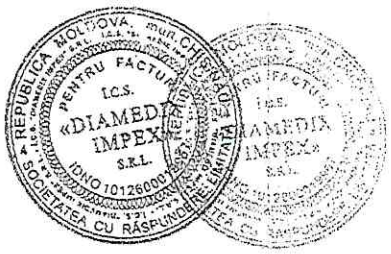
Unterschrift / *Signature*

Dr. Wilhelm Schuy

Name /*Name*

2009-08-05

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



SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):*
Kontroll-Plasma N	*Control Plasma N*

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

ORKE

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

ORKE 41

IVD-Kategorie / *IVD Category:*	
Sonstige	*Others*

Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	*Address (international):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*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]:*

REPUBLICA MOLDOVA mun. CHIŞINĂU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600010681 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600010681 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

Konformitätserklärung — *Declaration of Conformity*

CE

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):*
Kontroll-Plasma P	*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):	*Address (international):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*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*

CE

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 Ci-Trol 2	*Dade Ci-Trol 2*

Produkt-Nr. / *Product No. (REF):*
291071

Packungsgröße(n) / *Package Size(s) (REF):*
291071

IVD-Kategorie / *IVD Category:*
Sonstige / *Others*

Hersteller / *Manufacturer:*
Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	*Address (international):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*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]:*

REPUBLICA MOLDOVA, mun. CHIȘINĂU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012000019[illegible], SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Digitally signed by Marinescu Traian Alin
Date: 2019.11.04 08:57:48 EET
Reason: MoldSign Signature
Location: Moldova

Sysmex SYSMEX CORPORATION
Address : 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
Phone : 81-78-265-0500
Facsimile : 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: 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