

REPUBLIC OF THE PHILIPPINES)
EMBASSY OF THE REPUBLIC OF THE PHILIPPINES) S. S.
TOKYO, JAPAN)
X

AUTHENTICATION

PETE RAYMOND V. DELFIN, Consul of the Republic
of the Philippines, in and for Tokyo, Japan, duly commissioned and qualified to act
as such hereby **CERTIFY THAT**

MR. KAZUTOYO OYABE
Official, Consular & Migration Policy Division
Ministry of Foreign Affairs, Japan

whose signature is affixed to the annexed

STATEMENT OF ATSUSHI HORI
MANAGER, REGULATORY AFFAIRS DEPARTMENT
TERUMO CORPORATION
DATED 09 JULY 2007

was at the time he signed the document on **10 July 2007**
an **Official** in and for Japan,
duly authorized to sign the same, and that full faith and credit are and ought to be
given to his/her official act, and I verily believe that the signature affixed thereto
is genuine.

The Embassy of the Republic of the Philippines assumes no responsibility
for the contents of the aforesaid instrument.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal
of the Embassy of the Republic of the Philippines at the City of Tokyo, Japan,
this 11th day of July, 2007.

Doc. No. 62261
Series of 20 07
Service No. 21327
Fee paid : Y5,250
O. R. No. : 0016




PETE RAYMOND V. DELFIN
Consul

TERUMO

TERUMO CORPORATION

Head Office

44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
Telephone:0313374-8111 Facsimile:0313374-3619

Shonan Center

1500 Inokuchi, Naka-machi, Ashigarakami-gun, Kanagawa Pref. 259-0151, Japan
Telephone:0465181-4111 Facsimile:0465181-4229



Certificate
The Certification Body of
TUV Rheinland Product Safety GmbH

hereby certifies that the organization

Date: July 9, 2007

**Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya City
SHIZUOKA PREFECTURE 418-0015
JAPAN**

To whom it may concern,

STATEMENT

We, TERUMO CORPORATION hereby state that attached documents are true and identical copies of the original documents.

Design and Manufacturing of Medical Devices

Product groups: see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2003

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No. SA 6016297 0001

Approved Report No. 13008025 003



28.09.2010

Atsushi Hori
Manager
Regulatory Affairs Department
TERUMO CORPORATION

Cologne, 03.11.2006



Certification Body


Dr. H. Lüdemann

TUV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln

TX: (+49221) 905-1571 Fax: (+49221) 905-1520 E-Mail: certification@tuvsau.com <http://www.tuvsau.com>



Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

**Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya City
SHIZUOKA PREFECTURE 418-0015
JAPAN**

has established and applies a quality management system for medical devices
for the following scope:

Design and Manufacturing of Medical Devices

Product groups: see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2003

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60016297 0001

An audit was performed. Report No.: 12008025 003

This Certificate is valid until: 29.09.2010



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Cologne, 03.11.2006



Certification Body


Dr. H. Lüdemann

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln

Tel.: (+49/221) 806 - 1371 Fax: (+49/221) 806 - 3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety



TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Doc. 1/2, Rev. 0

Attachment to
Registration No.: SX 60016297 0001
Report No.: 12008025 003

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya City
SHIZUOKA PREFECTURE 418-0015
JAPAN

Scope: Product groups:

- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Extra-corporeal Membrane Oxygenator
- Haemodialysis Hollow-Fiber Dialyser
- Catheter Connector
- Catheter Guide Wire Accessories
- Angiographic Catheter
- Stents
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Catheter Introducer
- Air/Fluid Level Detector for Heart-Lung Bypass System Module
- Temperature Control Unit for Heart-Lung Bypass System Module



Akkreditiert durch
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bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Cologne, 03.11.2006



H. Lüdemann
Dr. H. Lüdemann



TÜV Rheinland

Doc. 2/2, Rev. 0

Product Safety GmbH

Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: SX 60016297 0001
Report No.: 12008025 003

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya City
SHIZUOKA PREFECTURE 418-0015
JAPAN

Scope: Product groups:

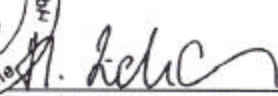
- Catheter Systems
- Oxygenator Systems
- Epidural Anesthesia Kit
- Extension Tube
- Urinary Drainage Bag
- General Medical Disposables
- Syringe Infusion Pump
- Infusion Pump
- Clinical Electronic Thermometer
- Clinical Electronic Blood-Pressure Meter
- Vital Sign Measuring Equipment
- Medical Equipment for Blood Collection and Artificial Organ



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Cologne, 03.11.2006




Dr. H. Lüdemann



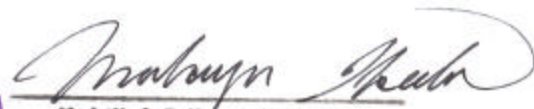
Registration No. 1248, 2007

NOTARIAL CERTIFICATE

I, the undersigned Notary, do hereby certify that Akiko NIITSU, an agent of Atsushi HORI, Manager, Regulatory Affairs Department of TERUMO CORPORATION who has been authorized to sign the attached document, has stated in my very presence that said Atsushi HORI acknowledged himself to have signed the attached document, and that his signature is true and genuine.

Dated: on this 10th day of July, 2007.




MAKAZU IKEDA
NOTARY