

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

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

**Design and development, manufacture and distribution
of active, non-active medical devices and IVD
medical devices and servicing of active medical devices
(see attachments for products and sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date: 2017-08-30
Certificate Registration No.: SX 60121908 0001
An audit was performed. Report No.: 12031336 001
This Certificate is valid until: 2019-03-30

Certification Body



Date 2017-08-18




M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60121908 0001
Report No.: 12031336 001

Organization: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Scope:

Products included:

- Solution Administration Sets
- Needles
- Syringes
- IV Catheters
- Blood Collection Systems
- Sterile Tube Connecting Systems
- Blood Glucose Monitoring Systems
- Stents
- Catheter and Guide Wire Systems
- Oxygenator Systems
- Extension Tube
- Blood Transfusion Systems
- Apheresis Systems
- Filter Systems
- Infusion Pumps
- Syringe Infusion Pumps

Certification Body



Date: 2017-08-18

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60121908 0001
Report No.: 12031336 001

Organization: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Scope:

Products included:

- Clinical Electronic Blood-Pressure Monitors
- Clinical Electronic Thermometer
- Medical Equipments for Blood Collection
- Medical Equipments for APD Systems
- Vascular Grafts
- Coronary Optical Coherence Tomography Systems
- Prefillable Syringes

Site included:

Terumo Corporation - Tokyo Office
3-20-2, Nishi-Shinjuku, Shinjuku-ku, Tokyo, 163-1450 Japan


Scope:

Activities related to corporate management processes

Certification Body



Date: 2017-08-18


M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60121908 0001
Report No.: 12031336 001

Organization: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Scope:

Sites included:

Terumo Corporation - Shonan Center
1500, Inokuchi, Nakai-machi, Ashigarakami-gun, Kanagawa,
259-0151, Japan

Scope:

Activities related to customer communication processes and
distribution of active, non-active and IVD medical devices

Terumo Corporation Blood Management Company
Transfusion Business Group - c/o Terumo BCT Japan Inc.,
Takanawa Office
3-20-14 Higashi-Gotanda, Shinagawa-ku, Tokyo,
141-0022, Japan

Scope:

Activities related to corporate management processes

Certification Body



Date: 2017-08-18

M. Aihara
M.Sc. M. Aihara

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60121893 0001

Report No.: 12031336 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60077473 0001

Expiry Date: 2022-08-29

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-08-30

Date: 2017-08-25



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60121893 0001
Report No.: 12031336 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

Date: 2017-08-25



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60121893 0001
Report No.: 12031336 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products included:

- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer

Date: 2017-08-25



Notified Body

M. Aihara
M.Sc. M. Aihara

CERTIFICATE

Number: 2125269

The management system of:

TERUMO CLINICAL SUPPLY CO., LTD.

3 Kawashima-Takehayamachi
Kakamigahara
Gifu 501-6024
Japan

including the implementation meets the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

Scope:

Design, development and manufacture of catheters, guide-wires, sheath introducers, vascular access ports, and medical tubing for use in the area of interventional radiology and interventional cardiology.

Certificate expiry date: 1 June 2021
Certificate effective date: 5 June 2018
Certified since: 12 May 2009

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60115912 0001

Report No.: 31690642 001

Manufacturer: Terumo Medical Corporation
950 Elkton Boulevard
Elkton MD 21921
USA

Products: Introducer Kits and Guiding Sheaths
Aspects of manufacture concerned with securing and
maintaining sterility of Vascular Compression Cuff
Replaces Approval, Registration No.: HD 60109918 0001

Expiry Date: 2022-02-16

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-02-17

Date: 2017-02-09



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.