

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Terumo Corporation  
Ashitaka Plant  
150, Maimaigi-cho  
Fujinomiya-shi  
Shizuoka, 418-0015  
Japan**

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

**see attachments for scope of certification**

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: 2017-07-10  
Certificate Registration No.: SX 60120892 0001  
An audit was performed. Report No.: 12031333 001  
This Certificate is valid until: 2019-03-30

Certification Body



Date 2017-07-03



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**

**Attachment to  
Certificate**

**Registration No.:** SX 60120892 0001  
**Report No.:** 12031333 001

**Organization:** Terumo Corporation  
Ashitaka Plant  
150, Maimaigi-cho  
Fujinomiya-shi  
Shizuoka, 418-0015  
Japan

**Scope:**

Design and Development, Manufacture, Service and Sterilization (ETO) of

- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Haemoconcentration Filter
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Blood Reservoir
- Angiographic Catheter
- Stents
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Catheter Introducer
- Wire Twister
- Guiding Catheter
- Extension Tube
- Coronary Imaging Catheters
- Centrifugal Pump

**Certification Body**



**Date:** 2017-07-03

*M. Aihara*  
**M.Sc. M. Aihara**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 2/4, Rev.0

**Attachment to  
Certificate**

**Registration No.:** SX 60120892 0001  
**Report No.:** 12031333 001

**Organization:** Terumo Corporation  
Ashitaka Plant  
150, Maimaigi-cho  
Fujinomiya-shi  
Shizuoka, 418-0015  
Japan

**Scope:**

Design and Development, Manufacture, Service and Sterilization (ETO) of

- Temperature Control Unit for Heart-Lung Bypass System Module
- Air/Fluid Level Detector for Heart-Lung Bypass System Module
- Centrifugal Pump Controller
- Syringe Infusion Pump
- Infusion Pump
- Clinical Electronic Thermometer
- Deep Body Temperature Monitor
- Clinical Electronic Blood-Pressure Meter
- Medical Equipment for Blood Collection
- Medical Equipment for APD Systems
- Sterile Tube Connecting Systems
- Coronary Optical Coherence Tomography Systems
- Blood Glucose Meters for Blood Glucose Monitoring Systems

**Certification Body**



**Date:** 2017-07-03

*M. Aihara*  
**M.Sc. M. Aihara**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 3/4, Rev.0

**Attachment to  
Certificate**

**Registration No.:** SX 60120892 0001  
**Report No.:** 12031333 001

**Organization:** Terumo Corporation  
Ashitaka Plant  
150, Maimaigi-cho  
Fujinomiya-shi  
Shizuoka, 418-0015  
Japan

**Scope:**

Sites included:

Terumo Corporation Ashitaka Plant  
150, Maimaigi-cho, Fujinomiya-shi, Shizuoka, 418-0015, JAPAN

Scope:

Activities related to Design and Development, Manufacture  
and Sterilization (ETO)

Products:

Medical Devices listed on Doc. 1/4 and 2/4

Terumo Corporation - Tokyo Office

3-20-2, Nishi-Shinjuku, Shinjuku-ku, Tokyo, 163-1450 JAPAN

Scope:

Activities related to Service

Products:

Medical Devices listed on Doc. 1/4 and 2/4

**Certification Body**



**Date:** 2017-07-03

  
**M.Sc. M. Aihara**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60120892 0001  
**Report No.:** 12031333 001

**Organization:** Terumo Corporation  
Ashitaka Plant  
150, Maimaigi-cho  
Fujinomiya-shi  
Shizuoka, 418-0015  
Japan

**Scope:**

Sites included:

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

Scope:

Activities related to Design and Development and Service  
Products:

Medical Devices listed on Doc. 1/4 and 2/4

Terumo Corporation - ME Center (Nagaizumi)  
1002-1, Shimonagakubo, Nagaizumi-cho, Sunto-gun,  
Shizuoka, 411-0934 JAPAN

Scope:

Activities related to Design and Development, Manufacture  
and Service

Products:

Medical Devices listed on Doc. 1/4 and 2/4

Monitoring Systems

**Certification Body**



**Date:** 2017-07-03

  
**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**

**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**

**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

© Integral publication of this certificate and adjoining reports is allowed





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.