TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

TÜVRheinland®

Doc. 1/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2017-08-18

M.Aihara

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2017-08-18

M.Sc. M. Aihara

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Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2017-08-18

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.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.

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Doc. 1/2, Rev. 0

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Date: 2017-08-25

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev. 0

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2017-08-25

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

MGMT. SYS.
RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

EC Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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.