TÜVRheinland®

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

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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

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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

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2017-07-03

M.Sc. M. Aihara

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TÜVRheinland®

Doc. 2/4, Rev.0

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

- 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

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Date: 2017-07-03

M.Aihara

M.Sc. M. Aihara

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Doc. 3/4, Rev.0

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 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

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2017-07-03

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Doc. 4/4, Rev.0

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

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2017-07-03

M. Aihara

M.Sc. M. Aihara

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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

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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

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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

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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

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