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

Digitally signed by Grabazei Alexandru
Date: 2019.03.28 20:17:17 EET
Reason: MoldSign Signature
Location: Moldova

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

M.Aihara

Date: 2017-08-18

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

TÜVRheinland®

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

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 554734**

Issued To: **Terumo Corporation**
44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
151-0072
Japan

In respect of:

The Design and Manufacture of Balloon Dilatation Catheters, PTCA Guidewires, Angiographic Catheters, MicroGuide catheters, Coronary Imaging Catheters and coronary optical coherence tomography system.

Those aspects of Annex II related to securing and maintaining the sterility of the MDU cover, Extension Wires, and related accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **30 October 2009** Date: **01 August 2014** Expiry Date: **12 August 2019**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 554734**
Date:	**01 August 2014**
Issued To:	**Terumo Corporation** **44-1, 2-chome** **Hatagaya** **Shibuya-ku** **Tokyo** **151-0072** **Japan**

Subcontractor:	**Service(s) supplied**
Terumo Corporation Ashitaka Plant 150, Maimaigi-cho, Fujinomiya City, Shizuoka Prefecture 418-0015 Japan	**ETO Sterilization** **Manufacture**
Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium	**EU Representative**

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By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 554734**

Date: **01 August 2014**

Issued To: **Terumo Corporation**
44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
151-0072
Japan

Date	Reference Number	Action
30 October 2009	7443727	First Issue – Transfer from another Notified Body
17 September 2010	7560390	Certificate renewal
23 December 2011	7778290	Addition of "Angiographic Catheters" to the scope of the certificate. Additional service supplied for ETO sterilization at the Terumo Ashitaka Plant.
30 March 2012	7730762	Update to scope of certificate to add Coronary Imaging Catheters.
21 December 2012	7916383	Extension to scope to include LUNAWAVE.
18 April 2013	7948395 7959985	Optical Coherence Tomography System (LUNAWAVE) was introduced under 7916383 in Dec 2012. Brand name 'LUNAWAVE' has now been removed from scope. This does not affect the device types covered by the certificate. Extension of scope to include Class I sterile MDU cover and accessories.
4 June 2013	7974363	Extension to scope to include micro-guide catheters.
4 June 2014	8164373	Certificate renewal.
1 August 2014	8196034	Addition of "PTCA Guidewires" and "sterility of…Extension Wires" to the scope.

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.

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

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

No.DOC-DQ010- 0246
Rev.10

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

RADIFOCUS Torque Device

Product : Wire Twister

declare that the above products of **Class I sterile** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 5 of the Directive, relating to the "EC Declaration of Conformity" set out in Annex VII, combined with the provisions set out in Annex V "Production Quality Assurance" and by certification of Annex V limited to the aspects of the manufacture concerned with securing and maintaining sterile conditions, under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: DD 60121892 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, August 30, 2017
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

X X * R F 0 2 M
1 2 3 4 5 6 7 8

Character number	Characters	Meaning
1-2	Product type	XX : other (Accessory device)
3	Destination	* : for export
4-5	Product group	RF : RADIFOCUS system
6-7	Accessory device type	02 : Torque Device
8	Package indication	M : Multi-language