bsi.

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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by the named entity or on their behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Digitally signed by Grabazei Alexandru
Date: 2019.09.18 15:48:03 EEST
Reason: MoldSign Signature
Location: Moldova

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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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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.

TÜVRheinland®

EC Design-Examination Certificate
Directive 93/42/EEC Annex II, Section 4
Medical Devices

Registration No.: ID 60114894 0001

Report No.: 21255836 001

Manufacturer:

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Product Identification:

Catheter, Angiography
RADIFOCUS OPTITORQUE

(see attachment for products included)
Replaces certificate, Registration No.: ID 60041981 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2021-11-10

Effective Date: 2016-11-11

Date: 2016-11-09

Notified Body

TÜV Rheinland LGA Products GmbH

Dipl.-Ing. S. Pane

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
Registration No.: **ID 60114894 0001**
Report No.: **21255836 001**

Manufacturer: **TERUMO EUROPE N.V.**
Interleuvenlaan 40
3001 Leuven
Belgium

Radifocus Optitorque

Product code system

(1) Thoracic use

R	H	-	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning
1-2	Product name RH: Radifocus® Optitorque™
3	Manufacturing site -: TERUMO Europe N.V.
4	Outer diameter of catheter Indication: 4, 5 6 Size (Fr.): 4 (1.40 mm); 5 (1.70 mm); 6 (2.00 mm)
5-8	Tip shape: Character (A~Z, 0~9)
9	Number of side holes Indication: 0 ~ 9 Number of side holes: 0 - 9
10	Catheter Length
	Indication : 6 G 7 8 9 0 1 Length (cm): 60 65 70 80 90 100 110
11	Language used for the indications M: Multi-language indication

Date, 2016-11-09

Notified Body

Dipl.-Ing. S. Pane

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: **ID 60114894 0001**
Report No.: **21255836 001**

Manufacturer: **TERUMO EUROPE N.V.**
Interleuvenlaan 40
3001 Leuven
Belgium

Radifocus Optitorque

(2) Visceral & Cerebral use

R	H	-	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning
1-2	Product name RH: Radifocus® Optitorque™
3	Production site -: TERUMO Europe N.V.
4	Indication of catheter use A : visceral use B : cerebral use
5-6	Tip shape: Character (A~Z, 0~9)
7	Outer diameter of catheter Indication: 4, 5 Size (Fr.): 4 (1.40 mm); 5 (1.70 mm)
8	Availability of stopcock 1 : Without stopcock
9-10	Catheter Length
	Indication: 02 0G 07 08 09 10 11 Length (cm): 20 65 70 80 90 100 110
11	Languages used for the indication M: Multilanguage

TÜV Rheinland LGA Products GmbH
Notified Body

Date, 2016-11-09

Dipl.-Ing. S. Pane

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

TÜVRheinland®

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

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

TÜVRheinland®

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

M.Sc. M. Aihara

TÜVRheinland®

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

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Terumo Medical Corporation
950 Elkton Boulevard
Elkton MD 21921
USA

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

(see attachment for scope and additional 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:	2018-01-09
Certificate Registration No.:	SX 60125617 0001
An audit was performed. Report No.:	31690642 005
This Certificate is valid until:	2019-03-30

Certification Body

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

Date 2018-01-09

Dipl.-Ing. S. Pane

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®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60125617 0001
Report No.: 31690642 005

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

Scope:

Scope:
Design and Development, Manufacturing and Distribution of Disposable Sterile Medical Devices, including Introducer kits, Guiding Sheaths, and Vascular Compression Cuffs. Provision of contract gamma sterilization service in accordance with EN ISO 11137-1:2015

The scope of the certification also includes the following sites:

Terumo Medical Corporation
2101 Cottontail Lane
Somerset, NJ 08873, USA
Scope: Activities related to Distribution

Terumo Medical Corporation
4550 W. Van Buren Street, Suite B-103
Phoenix, AZ 85043, USA
Scope: Activities related to Distribution

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland

Date: 2018-01-09

Dipl.-Ing. S. Pane

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60125617 0001
Report No.: 31690642 005

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

Scope:

The scope of the certification also includes the following site:

Terumo Medical Corporation
8655 Commerce Drive, Suite 101
Southaven, MS 38671, USA
Scope: Activities related to Distribution

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland

Date: 2018-01-09

Dipl.-Ing. S. Pane

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.