

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



Date 2018-01-09



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 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




Dipl.-Ing. S. Pane

Date: 2018-01-09

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




Dipl.-Ing. S. Pane

Date: 2018-01-09



DECLARATION OF CONFORMITY

We, TERUMO MEDICAL CORPORATION
950 Elkton Blvd.
Elkton, Maryland USA 21921

being the manufacturer of:

Guiding Sheath

Product: Carotid Guiding Sheath
Renal Guiding Sheath
Peripheral Guiding Sheath


Classification: Class IIa
Rule: 7, Invasive Device

Hereby declares that the requirements of Annex II, excluding section 4 of the Directive 93/42/EEC have been met for the listed product. 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.

Under the supervision of TÜV Rheinland LGA Products GmbH (Registration No. HD60115912 0001) as the Notified Body according to Directive 93/42/EEC concerning medical devices with the Identification number 0197.


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

Elkton, Maryland USA / February 27, 2017
(Place of issue)


Kathleen Little, Ph.D.
VP, Quality and Regulatory Affairs

State of Maryland
County of Cecil

Subscribed and sworn to before me this 27 day of February month 2017 year.


Barbara C. Myers
Notary Public
My commission expires May 19, 2020





1	2	3	4	5	
R	Radifocus Group				
	S	Guiding Sheath			
Carotid	C	90 cm Sheath			
		0	1	6 Fr, Straight Shape (ST), TBV Valve	
		0	2	7 Fr, Straight Shape (ST), TBV Valve	
		0	3	6 Fr, Multipurpose Shape (MP), TBV Valve	
		0	4	7 Fr, Multipurpose Shape (MP), TBV Valve	
		0	5	6 Fr, Straight Shape (ST), CCV Valve	
		0	6	7 Fr, Straight Shape (ST), CCV Valve	
		0	7	6 Fr, Multipurpose Shape (MP), CCV Valve	
		0	8	7 Fr, Multipurpose Shape (MP), CCV Valve	
Peripheral	P	65 cm Sheath			
		0	1	6 Fr, Straight Shape (ST), CCV Valve	
		0	2	7 Fr, Straight Shape (ST), CCV Valve	
		0	3	6 Fr, Straight Shape (ST), TBV Valve	
		0	4	7 Fr, Straight Shape (ST), TBV Valve	
Renal	R	45 cm Sheath			
		0	1	6 Fr, Straight Shape (ST), CCV Valve	
		0	2	6 Fr, Hockey-Stick Shape (HS), CCV Valve	
		0	3	6 Fr, Multipurpose Shape (MP), CCV Valve	
		1	3	6 Fr, Renal Double Curve Shape (RDC), CCV Valve	
		1	4	6 Fr, Left Internal Mammary Artery Shape (LIMA), CCV Valve	
		0	4	7 Fr, Straight Shape (ST), CCV Valve	
		0	5	7 Fr, Hockey-Stick Shape (HS), CCV Valve	
		0	6	7 Fr, Multipurpose Shape (MP), CCV Valve	
		1	5	7 Fr, Renal Double Curve Shape (RDC), CCV Valve	
		1	6	7 Fr, Left Internal Mammary Artery Shape (LIMA), CCV Valve	
		0	7	6 Fr, Straight Shape (ST), TBV Valve	
		0	8	6 Fr, Hockey-Stick Shape (HS), TBV Valve	
		0	9	6 Fr, Multipurpose Shape (MP), TBV Valve	
		1	7	6 Fr, Renal Double Curve Shape (RDC), TBV Valve	
		1	8	6 Fr, Left Internal Mammary Artery Shape (LIMA), TBV Valve	
		1	0	7 Fr, Straight Shape (ST), TBV Valve	
		1	1	7 Fr, Hockey-Stick Shape (HS), TBV Valve	
		1	2	7 Fr, Multipurpose Shape (MP), TBV Valve	
		1	9	7 Fr, Renal Double Curve Shape (RDC), TBV Valve	
		2	0	7 Fr, Left Internal Mammary Artery Shape (LIMA), TBV Valve	



1	2	3	4	5	6	7	8
5	4	Destination					
		-					
5 Fr		5					
		Straight Shape (ST), CCV Valve, Extended Coating			0	1	
		Hockey Stick Shape, CCV Valve (HS)			0	2	
		Multipurpose Shape, CCV Valve (MP)			0	3	
		Renal Double Curve Shape, CCV Valve (RDC)			0	4	
		Left Internal Mammary Artery Shape (LIMA), CCV Valve			0	5	
6 Fr		6					
		Straight Shape (ST), CCV Valve, Extended Coating			0	1	
		Straight Shape (ST), TBV Valve, Extended Coating			0	6	
7 Fr		7					
		Straight Shape (ST), CCV Valve, Extended Coating			0	1	
		Straight Shape (ST), TBV Valve, Extended Coating			0	6	
8 Fr		8					
		Straight Shape (ST), CCV Valve, Extended Coating (45 & 90cm)			0	1	
		Straight Shape (ST), TBV Valve, Extended Coating (45 & 90cm)			0	6	
		Length	4	5	45 cm Sheath		
			6	5	65 cm Sheath		
			9	0	90 cm Sheath		



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.

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.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