

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
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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

DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**

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

being the manufacturer of:

RADIFOCUS Guide Wire M

Product : Catheter Guide Wire

declare that the above products of **Class III** 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, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 (Registration No.: HD 60121893 0001), and Annex II, Section 4 (Registration No.: ID 60116055 0001) under the supervision of TÜV Rheinland LGA Products GmbH, 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

RADIFOCUS GUIDEWIRE M Product code system

1) Without radiopaque tip marker

Standard type

R F * □ □ □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation								
1-2	Product name	RADIFOCUS GUIDE WIRE M							
3	Destination	* : for export							
4	Core wire flexibility	G : Standard H : Half stiff P : Stiff							
5	Tip configuration	A : Angled B : J-angled (3mm) C : J-angled (6mm) E : Double-angled N : J-angled (2mm) R : J-angled (1.5mm) S : Straight							
6-7	Outer diameter of guide wire	18			25				
		stiff-core type: 0.020"							
		other core types: 0.018"							
		32		35		38			
		0.032"		0.035"		0.038"			
8-9	Guide wire length	05	07	08	12	15	18		
		50 cm		70 cm		80 cm		120 cm	
		22		26		30		35	
		220 cm		260cm		300cm		350cm	
		400 cm		450 cm					
10	Flexible part length in the distal tip	1 : 1cm (short taper) 3 : 3cm (normal taper) 5 : 5cm (long taper) 8 : 8cm (long long taper)							
11	Languages used for the indications	M : Multilanguage							

High Flex Type

R F *

1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation									
1-2	Product name	RADIFOCUS GUIDE WIRE M								
3	Destination	*: for export								
4	Core wire flexibility	G : Standard H : Half stiff								
5	Tip configuration	J : Straight F : Angled								
6-7	Outer diameter of guide wire	18	25	32	35	38				
		0.018"	0.025"	0.032"	0.035"	0.038"				
8-9	Guide wire length	12	15	18	22	26	30	40	45	
		120cm	150cm	180cm	220cm	260cm	300cm	400cm	450cm	
10	Flexible part length in the distal tip	3 : 3cm (normal taper)								
11	Languages used for the indications	M : Multilanguage								

Super-Flex Type

R F * □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation				
1-2	Product name	RADIFOCUS GUIDE WIRE M			
3	Destination	*: for export			
4	Core wire flexibility	G : Standard			
5	Tip configuration	V : J-angled (2mm)			
6-7	Outer diameter of guide wire	35: 0.035"			
8-9	Guide wire length	15	18	20	22
		150 cm	180 cm	200 cm	220 cm
10	Flexible part length in the distal tip	1 : 1cm (short taper)			
11	Languages used for the indications	M : Multilanguage			

Shapeable Type (E Type)

R E * □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation					
1-2	Product name	RADIFOCUS GUIDE WIRE M				
3	Destination	*: for export				
4	Core wire flexibility	G : Standard				
5	Tip configuration	L : Straight K : Angled				
6-7	Outer diameter of guide wire	18	25	32	35	38
		0.018"	0.025"	0.032"	0.035"	0.038"
8-9	Guide wire length	12	15	18	22	26
		120cm	150cm	180cm	220cm	260cm
10	Flexible part length in the distal tip	3 : 3cm (normal taper)				
11	Languages used for the indications	M : Multi-language				

2) With radiopaque tip marker

R F * R □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Denotation			
1, 2, 4	Product name	RADIFOCUS GUIDE WIRE M		
3	Destination	*: for export		
5	Tip configuration (Angled)	A : 45° B : 70°		
6-7	Outer diameter of guide wire	10	14	16
		0.011"	0.014"	0.016"
8-9	Guide wire length	18 : 180cm		
10	Flexible part length in the distal tip	8 : 8cm (long long taper)		
11	Accessory supplied with the guide wire	T : Torque device		
12	Languages used for the indications	M : Multilanguage		

RADIFOCUS GUIDEWIRE M manufactured by TVC Product code system

Standard type

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

Position	Meaning of indication						
1-2	Product type	RADIFOCUS GUIDE WIRE M					
3	Destination	+ / * for worldwide excluding Japan					
4	Core wire flexibility	G : Standard H : Half stiff P : Stiff					
5	Tip configuration	A : Angled S : Straight					
6-7	Outer diameter of guide wire	18			25		
		stiff-core type: 0.020" / 0.51 mm other core types: 0.018" / 0.46 mm			0.025" / 0.64 mm		
		32		35		38	
		0.032" / 0.81 mm	0.035" / 0.89 mm		0.038" / 0.97 mm		
8-9	Guide wire length	05	07	08	12	15	18
		50 cm	70 cm	80 cm	120 cm	150 cm	180 cm
		22	26				
		220 cm	260cm				
10	Flexible part length in distal tip	1 : 1cm (short taper) 3 : 3cm (normal taper) 5 : 5cm (long taper) 8 : 8cm (long long taper)					
11	Languages used for the indications	M : Multilanguage					