

RADIFOCUS®  
**GUIDE WIRE FAMILY**



GLIDE WITH  
**CONFIDENCE**

# RADIFOCUS® Guide Wire GT

With Gold Coil

- Nitinol guidewire covered with polyurethane containing tungsten and hydrophilic M Coat™ as well as distal 2 cm gold coil
- Small diameters, long-tapered core and distal pre-shaped curves for superselective access of peripheral, coronary and cerebral vasculature

## ■ ORDERING INFORMATION



Product code	Outer diameter	Overall length	Flexible tip length	Tip shape
RG*GA1218SM	0.012" / 0.30 mm	180 cm	25 cm	Angled 45° x 4 mm
RG*GE1218SM	0.012" / 0.30 mm	180 cm	25 cm	Angled 90° x 4 mm
RG*GJ1218SM	0.012" / 0.30 mm	180 cm	25 cm	Angled 1.5 mm J curve
RG*GW1218M	0.012" / 0.30 mm	180 cm	25 cm	Double angled 90° + 150°
RG*GA1220SM	0.012" / 0.30 mm	200 cm	25 cm	Angled 45° x 4 mm
RG*GE1220SM	0.012" / 0.30 mm	200 cm	25 cm	Angled 90° x 4 mm
RG*GJ1220SM	0.012" / 0.30 mm	200 cm	25 cm	Angled 1.5 mm J curve
RG*GW1220M	0.012" / 0.30 mm	200 cm	25 cm	Double angled 90° + 150°
RG*GA1418SM	0.014" / 0.036 mm	180 cm	25 cm	Angled 45° x 4 mm
RG*GE1418SM	0.014" / 0.036 mm	180 cm	25 cm	Angled 90° x 4 mm
RG*GW1418M	0.014" / 0.036 mm	180 cm	25 cm	Double Angled 90° + 150°
RG*GA1420SM	0.014" / 0.036 mm	200 cm	25 cm	Angled 45° x 4 mm
RG*GE1420SM	0.014" / 0.036 mm	200 cm	25 cm	Angled 90° x 4 mm
RG*GW1420M	0.014" / 0.036 mm	200 cm	25 cm	Double Angled 90° + 150°
RG*GA1618SM	0.016" / 0.41 mm	180 cm	25 cm	Angled 45° x 4 mm
RG*GA1618FM	0.016" / 0.41 mm	180 cm	35 cm	Angled 45° x 4 mm
RG*GE1618FM	0.016" / 0.41 mm	180 cm	35 cm	Angled 90° x 4 mm
RG*GW1618M	0.016" / 0.41 mm	180 cm	35 cm	Double angled 90° + 150°
RG*GV1618SM	0.016" / 0.41 mm	180 cm	25 cm	Double Angled 90° + 90°
RG*GA1620FM	0.016" / 0.41 mm	200 cm	35 cm	Angled 45° x 4 mm
RG*GE1620FM	0.016" / 0.41 mm	200 cm	35 cm	Angled 90° x 4 mm
RG*GW1620M	0.016" / 0.41 mm	200 cm	35 cm	Double angled 90° + 150°
RG*GJ1620FM	0.016" / 0.41 mm	200 cm	35 cm	Angled 1.5 mm J curve

# RADIFOCUS® Guide Wire M

Stiff

- Nitinol guidewire covered with polyurethane containing tungsten and hydrophilic M Coat™
- Stiffer shaft<sup>1</sup> designed for tight, stenotic, tortuous and narrow vessels

## ■ ORDERING INFORMATION

Product code	Wire type	Outer diameter	Overall length	Flexible tip length	Tip shape
RF-PA18153M	Stiff	0.020" / 0.51 mm	150 cm	3 cm	Angled 
RF-PA18263M	Stiff	0.020" / 0.51 mm	260 cm	3 cm	
RF-PA25153M	Stiff	0.025" / 0.64 mm	150 cm	3 cm	
RF-PA25183M	Stiff	0.025" / 0.64 mm	180 cm	3 cm	
RF-PA25263M	Stiff	0.025" / 0.64 mm	260 cm	3 cm	
RF-PA35083M	Stiff	0.035" / 0.89 mm	80 cm	3 cm	
RF-PA35151M	Stiff	0.035" / 0.89 mm	150 cm	1 cm	
RF*PA35153M	Stiff	0.035" / 0.89 mm	150 cm	3 cm	
RF*PA35183M	Stiff	0.035" / 0.89 mm	180 cm	3 cm	
RF*PA35188M	Stiff	0.035" / 0.89 mm	180 cm	8 cm	
RF-PA35263M	Stiff	0.035" / 0.89 mm	260 cm	3 cm	
RF-PA35303M	Stiff	0.035" / 0.89 mm	300 cm	3 cm	
RF-PA38153M	Stiff	0.038" / 0.97 mm	150 cm	3 cm	
RF-PA38183M	Stiff	0.038" / 0.97 mm	180 cm	3 cm	
RF-PA38263M	Stiff	0.038" / 0.97 mm	260 cm	3 cm	
RF-PS25153M	Stiff	0.025" / 0.64 mm	150 cm	3 cm	Straight 
RF-PS25263M	Stiff	0.025" / 0.64 mm	260 cm	3 cm	
RF-PS35083M	Stiff	0.035" / 0.89 mm	80 cm	3 cm	
RF-PS35153M	Stiff	0.035" / 0.89 mm	150 cm	3 cm	
RF-PS35183M	Stiff	0.035" / 0.89 mm	180 cm	3 cm	
RF-PS35263M	Stiff	0.035" / 0.89 mm	260 cm	3 cm	
RF-PS35453M	Stiff	0.035" / 0.89 mm	450 cm	3 cm	
RF-PS38083M	Stiff	0.038" / 0.97 mm	80 cm	3 cm	
RF-PS38153M	Stiff	0.038" / 0.97 mm	150 cm	3 cm	
RF-PS38183M	Stiff	0.038" / 0.97 mm	180 cm	3 cm	

1. Barbeau G. et al. Radial Loop and Extreme Vessel Tortuosity in the Transradial Approach: Advantage of Hydrophilic-Coated Guidewires and Catheters. Catheterization and Cardiovascular Interventions 59:442-450 (2003).

1. Compared to Radifocus® Guide Wire M Standard.

## 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 60145252 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, February 10, 2020

(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	<b>G</b> : Standard <b>H</b> : Half stiff <b>P</b> : Stiff					
5	Tip configuration	<b>A</b> : Angled <b>B</b> : J-angled (3mm) <b>C</b> : J-angled (6mm) <b>E</b> : Double-angled <b>N</b> : J-angled (2mm) <b>R</b> : J-angled (1.5mm) <b>S</b> : Straight					
6-7	Outer diameter of guide wire	<b>18</b>				<b>25</b>	
		stiff-core type: 0.020"					
		other core types: 0.018"					
		<b>32</b> 0.032"		<b>35</b> 0.035"		<b>38</b> 0.038"	
8-9	Guide wire length	<b>05</b>	<b>07</b>	<b>08</b>	<b>12</b>	<b>15</b>	<b>18</b>
		50 cm	70 cm	80 cm	120 cm	150 cm	180 cm
		<b>22</b>	<b>26</b>	<b>30</b>	<b>35</b>	<b>40</b>	<b>45</b>
		220 cm	260cm	300cm	350cm	400 cm	450 cm
10	Flexible part length in the distal tip	<b>1</b> : 1cm (short taper) <b>3</b> : 3cm (normal taper) <b>5</b> : 5cm (long taper) <b>8</b> : 8cm (long long taper)					
11	Languages used for the indications	<b>M</b> : 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	<b>G</b> : Standard <b>H</b> : Half stiff								
5	Tip configuration	<b>J</b> : Straight <b>F</b> : Angled								
6-7	Outer diameter of guide wire	<b>18</b>	<b>25</b>	<b>32</b>	<b>35</b>	<b>38</b>				
		0.018"	0.025"	0.032"	0.035"	0.038"				
8-9	Guide wire length	<b>12</b>	<b>15</b>	<b>18</b>	<b>22</b>	<b>26</b>	<b>30</b>	<b>40</b>	<b>45</b>	
		120cm	150cm	180cm	220cm	260cm	300cm	400cm	450cm	
10	Flexible part length in the distal tip	<b>3</b> : 3cm (normal taper)								
11	Languages used for the indications	<b>M</b> : 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	<b>G</b> : Standard		
5	Tip configuration	<b>V</b> : J-angled (2mm)		
6-7	Outer diameter of guide wire	<b>35</b> : 0.035"		
8-9	Guide wire length	<b>15</b>	<b>18</b>	<b>20</b>
		150 cm	180 cm	200 cm
10	Flexible part length in the distal tip	<b>1</b> : 1cm (short taper)		
11	Languages used for the indications	<b>M</b> : 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)	<b>A</b> : 45° <b>B</b> : 70°		
6-7	Outer diameter of guide wire	<b>10</b>	<b>14</b>	<b>16</b>
		0.011"	0.014"	0.016"
8-9	Guide wire length	<b>18</b> : 180cm		
10	Flexible part length in the distal tip	<b>8</b> : 8cm (long long taper)		
11	Accessory supplied with the guide wire	<b>T</b> : Torque device		
12	Languages used for the indications	<b>M</b> : 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	<b>G</b> : Standard <b>H</b> : Half stiff <b>P</b> : Stiff							
5	Tip configuration	<b>A</b> : Angled <b>S</b> : Straight							
6-7	Outer diameter of guide wire	<b>18</b>			<b>25</b>				
		stiff-core type: 0.020" / 0.51 mm other core types: 0.018" / 0.46 mm							
		<b>32</b>		<b>35</b>		<b>38</b>			
		0.032" / 0.81 mm		0.035" / 0.89 mm		0.038" / 0.97 mm			
8-9	Guide wire length	<b>05</b>	<b>07</b>	<b>08</b>	<b>12</b>	<b>15</b>	<b>18</b>		
		50 cm		70 cm		80 cm		120 cm	
		150 cm		180 cm					
		220 cm		260cm					
10	Flexible part length in distal tip	<b>1</b> : 1cm (short taper) <b>3</b> : 3cm (normal taper) <b>5</b> : 5cm (long taper) <b>8</b> : 8cm (long long taper)							
11	Languages used for the indications	<b>M</b> : Multilanguage							

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60145252 0001

**Report No.:** 12031336 018

**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 60121893 0001

**Expiry Date:** 2024-05-26

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:** 2019-12-23

**Date:** 2019-12-23



**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 60145252 0001  
**Report No.:** 12031336 018

**Manufacturer:** Terumo Corporation  
44-1, 2-chome, Hatagaya  
Shibuya-Ku, Tokyo  
151-0072 Japan

**Products included:**

- Blood Bags
- Blood Donor Set
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet



**Notified Body**

*M. Aihara*

**Date: 2019-12-23**

**M.Sc. M. Aihara**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60145252 0001  
**Report No.:** 12031336 018

**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

**Notified Body**



**M.Sc. M. Aihara**



**Date: 2019-12-23**



# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1485480-1

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

Scope: Design and Development, Manufacture, Distribution and Service of

- Angiographic Catheter and Accessories
- Anti-adhesion System
- Balloon Dilatation Catheter
- Blood Collection/Transfusion Device and Accessories
- Blood Glucose Monitoring system
- Cartridge Injection System
- Catheter Introducer and Accessories
- Electronic Sphygmomanometer
- Electronic Thermometer
- Embolization Prosthesis and Accessories
- Endoscopic Vessel Harvesting System
- Extracorporeal Circulation Device and Accessories
- Falloposcopic Tuboplasty Device and Accessories
- Guide Wire and Accessories
- Guiding/Micro Catheter and Accessories
- Infusion Pump
- Infusion Set and Accessories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150241635-301  
Effective date: 2021-08-30  
Expiry date: 2023-08-29  
Issue date: 2021-08-29



*Michihara*

Michiaki Aihara  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1485480-1

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

- Intravascular Imaging Catheter and Accessories
- Intravascular Imaging System and Accessories
- Intravenous Catheter
- Left-Ventricular Assist System
- Needle
- Open-heart surgery devices and Accessories
- Oral Care Device and Accessories
- Peritoneal Dialysis Device and Accessories
- Pneumatically-powered Massager
- Prefillable Syringe
- Pulse Oximeter
- Radial Artery Hemostasis Device and Accessories
- Stent System
- Syringe
- Syringe Infusion Pump
- Syringe with Needle
- Thrombus Removal Device
- Tube Catheter and Accessories
- Urine test strip
- Vascular Closure Device
- Vascular Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

Report No.: 150241635-301  
Effective date: 2021-08-30  
Expiry date: 2023-08-29  
Issue date: 2021-08-29



*Michihara*

Michiaki Aihara  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1485480-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Terumo Corporation 44-1, 2-chome, Hatagaya Shibuya-ku, Tokyo 151-0072 Japan	Aspects related to Design and Development, Manufacture, Distribution and Service.
/02	c/o Terumo Corporation - Tokyo office 3-20-2, Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Aspects related to Design and Development and activities related to corporate management processes.
/03	c/o Terumo Corporation, Shonan Center 1500, Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Aspects related to Distribution and activities related to customer communication processes.

Report No.: 150241635-301  
Effective date: 2021-08-30  
Expiry date: 2023-08-29  
Issue date: 2021-08-29



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