

Description

Characteristics

General specifications

Item specifications

NV-GS25153M	Standard Nitinol	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	Straight
NV-GA25153M	Standard Nitinol	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	45° Angled
NV-PA25153M	Stiff Nitinol	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	45° Angled
NV-PS25453M	Stiff Nitinol	0.025" (0.64 mm + 0.00 mm)*	450 cm	3 cm	Straight
NV-PA25453M	Stiff Nitinol	0.025" (0.64 mm + 0.00 mm)*	450 cm	3 cm	45° Angled
NV-GS32153M	Standard Nitinol	0.032" (0.81 mm + 0.00 mm)*	150 cm	3 cm	Straight
NV-GA32153M	Standard Nitinol	0.032" (0.81 mm + 0.00 mm)*	150 cm	3 cm	45° Angled
NV-GS32263M	Standard Nitinol	0.032" (0.81 mm + 0.00 mm)*	260 cm	3 cm	Straight
NV-GA32263M	Standard Nitinol	0.032" (0.81 mm + 0.00 mm)*	260 cm	3 cm	45° Angled
NV-GS32403M	Standard Nitinol	0.032" (0.81 mm + 0.00 mm)*	400 cm	3 cm	Straight
NV-GA32403M	Standard Nitinol	0.032" (0.81 mm + 0.00 mm)*	400 cm	3 cm	45° Angled
NV-GA35083M	Standard Nitinol	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	45° Angled
NV-PS35083M	Stiff Nitinol	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	Straight
NV-GS35123M	Standard Nitinol	0.035" (0.89 mm + 0.01 mm)*	120 cm	3 cm	Straight
NV-GA35123M	Standard Nitinol	0.035" (0.89 mm + 0.01 mm)*	120 cm	3 cm	45° Angled
NV-GS35153M	Standard Nitinol	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	Straight
NV-GA35153M	Standard Nitinol	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	45° Angled
NV-PS35153M1	Stiff Nitinol	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	Straight
NV-PS35153M	Stiff Nitinol	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	Straight
NV-PA35153M	Stiff Nitinol	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	45° Angled
NV-GS35183M	Standard Nitinol	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	Straight
NV-PS35183M	Stiff Nitinol	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	Straight
NV-GS35263M	Standard Nitinol	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	Straight
NV-GA35263M	Standard Nitinol	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	45° Angled
NV-PA35263M	Stiff Nitinol	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	45° Angled
NV-GS35403M	Standard Nitinol	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	Straight
NV-GA35403M	Standard Nitinol	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	45° Angled
NV-PS35403M	Stiff Nitinol	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	Straight

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

Doc. 1/2, Rev.0

**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

Mai'hara

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



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



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

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	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”				0.025”	
		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	150 cm	180 cm
		22	26	30	35	40	45
		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
		150 cm	180 cm	200 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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
		50 cm	70 cm	80 cm	120 cm	150 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				