

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	☐	☐	☐	☐	☐	☐	☐	☐	☐
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				