

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

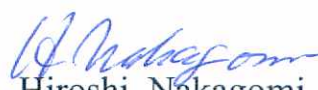
Product : Catheter Guide Wire

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.3 (Registration No.: HD 60026344 0001), and Annex II.4 (Registration No.: ID 60042796 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, March 13, 2012
(place and date of issue)


Hiroshi Nakagomi
General Manager
Quality Assurance Department
TERUMO CORPORATION

 **TERUMO®**

Appendix A - List of Code Number Structure

1) Without radiopaque tip marker

Standard type

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

Position	Meaning of indication													
1 – 2	Product type RF : 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 (3 mm) C: J-angled (6 mm) E: Double-angled N: J-angled (2 mm) R: J-angled (1.5 mm) S: Straight													
6 – 7	Outer diameter of guide wire													
	Character	18			25		32		35		38			
8 - 9	Diameter in	Stiff core type: 0.020" / 0.51 mm					0.025" /		0.032" /		0.035" /		0.038" /	
	inch/mm	Other core types: 0.018" /0.46 mm					0.64 mm		0.81 mm		0.89 mm		0.97 mm	
8 - 9	Guide wire length													
	Character	05	07	08	12	15	18	22	26	30	35	40		
	Length (cm)	50	70	80	120	150	180	220	260	300	350	400		
	Character	45												
	Length (cm)	450												
10	Flexible part length in distal tip 1 : 1 cm (short taper) 3: 3 cm (normal taper) 5: 5 cm (long taper) 8: 8 cm (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

Position	Meaning of indication										
1 – 2	Product type RF : Radifocus® Guide Wire M										
3	Destination * : for export										
4	Core wire flexibility G: Standard H: Half Stiff										
5	Tip configuration: F: Angled J: Straight										
6 - 7	Outer diameter of guide wire										
	Character	18		25		32		35		38	
	Diameter in inch/mm	0.018" / 0.46 mm		0.025" / 0.64 mm		0.032" / 0.81 mm		0.035" / 0.89 mm		0.038" / 0.97 mm	
8 - 9	Guide wire length										
	Character	12	15	18	22	26	30	40	45		
	Length (cm)	120	150	180	220	260	300	400	450		
10	Flexible part length in distal tip 3: 3 cm (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	

Position	Meaning of indication
1 - 2	Product type RF : Radifocus® Guide Wire M
3	Destination * : for export
4	Core wire flexibility G: Standard
5	Tip configuration: V: J-angled (2 mm)
6 - 7	Outer diameter of guide wire Character 35 Diameter in inch/mm 0.035" / 0.89 mm
8 - 9	Guide wire length Character 15 18 20 22 Length (cm) 150 180 200 220
10	Flexible part length in distal tip 1 : 1 cm (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

Position	Meaning of indication				
1 - 2	Product type RE : Radifocus® Guide Wire M				
3	Destination * : for export				
4	Core wire flexibility G: Standard				
5	Tip configuration: K: Angled L: Straight				
6 - 7	Outer diameter of guide wire				
	Character	18	25	32	35
	Diameter in inch/mm	0.018" / 0.46 mm	0.025" / 0.64 mm	0.032" / 0.81 mm	0.035" / 0.89 mm
8 - 9	Guide wire length				
	Character	12	15	18	22
	Length (cm)	120	150	180	220
10	Flexible part length in distal tip 3: 3 cm (normal taper)				
11	Languages used for the indications M: Multilanguage				

2) With radiopaque tip marker

R F * R ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 2 3 4 5 6 7 8 9 10 11 12

Position	Meaning of indication
1 - 2 & 4	Product type RF : Radifocus® Guide Wire M
3	Destination * : for export
5	Tip configuration: A: Angled 45° B: Angled 70°
6 - 7	Outer diameter of guide wire Character 10 14 16 18 Diameter in inch/mm 0.011"/0.28mm 0.014"/0.36mm 0.016"/0.41mm 0.018"/0.46 mm
8 - 9	Guide wire length Character 18 Length (cm) 180
10	Flexible part length in distal tip 8: 8 cm (long long taper)
11	Accessory supplied with the guide wire T: Torque device
12	Languages used for the indications M: Multilanguage