

**EC Design-Examination Certificate**  
**Directive 93/42/EEC Annex II, Section 4**  
**Medical Devices**

**Registration No.:** ID 60156558 0001

**Report No.:** 21262067 005

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

**Product**

**Identification:** Radifocus Guide Wire  
(see attachment for products included)  
Replaces Certificate, Registration No.: ID 60116055 0001

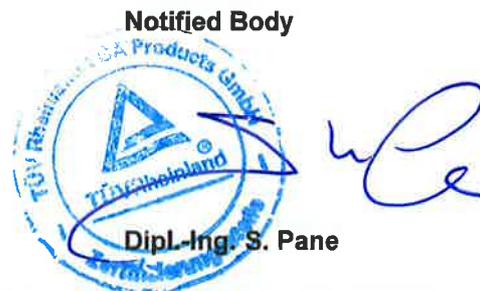
The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

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

**Effective Date:** 2021-05-14

**Date:** 2021-05-14

**Notified Body**



Dipl.-Ing. S. Pane

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

**Radifocus Guide Wire**

**Product code system**

(1) Radifocus Guide Wire M without radiopaque tip marker

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>							
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning
<b>1-2</b>	Product name <b>RF:</b> Radifocus Guide Wire M (Non-Shapeable Type) <b>RE:</b> Radifocus Guide Wire M(Shapeable Type)
<b>3</b>	Destination: *: for worldwide excluding Japan
<b>4</b>	Core wire flexibility <b>G:</b> Standard, <b>H:</b> Half stiff, <b>P:</b> Stiff

**Date: 2021-05-14**



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**Radifocus Guide Wire**

Position	Indication & Meaning									
<b>5</b>	Tip configuration <b>A:</b> Angled/standard type, <b>B:</b> 3mm J-angled/standard type, <b>C:</b> 6mm J-angled/standard type, <b>E:</b> Double-angled/standard type, <b>K:</b> Angled/Shapeable type <b>L:</b> Straight/Shapeable type <b>N:</b> 2mm J-angled/standard type, <b>R:</b> 1.5mm J-angled/standard type <b>S:</b> Straight/standard type, <b>F:</b> Angled/High Flex type <b>J:</b> Straight/High Flex Type <b>V:</b> 2mm J-angled/Super Flex type									
<b>6-7</b>	Outer diameter of guide wire Character <b>18</b> Diameter in Stiff core type: 0.020" / 0.51 mm inch/mm Other core types: 0.018" / 0.46 mm Character <b>25 32 35 38</b> 0.025" / 0.032" / 0.035" / 0.038" / 0.64 mm 0.81 mm 0.89 mm 0.97 mm									
<b>8-9</b>	Guide wire length									
	Indication	<b>05</b>	<b>07</b>	<b>08</b>	<b>12</b>	<b>15</b>	<b>18</b>	<b>20</b>	<b>22</b>	<b>26</b>
	Length (cm)	50	70	80	120	150	180	200	220	260
	Indication	<b>30</b>	<b>35</b>	<b>40</b>	<b>45</b>					
	Length (cm)	300	350	400	450					
<b>10</b>	Flexible part length in the distal tip									
	Indication	<b>1</b>	<b>3</b>	<b>5</b>	<b>8</b>					
	Length (cm)	1 (short taper)	3 (normal taper)	5 (long taper)	8 (long long taper)					
<b>11</b>	Languages used for labelling <b>M:</b> Multi-language									

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44-1, 2-chome, Hatagaya  
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Japan

**Radifocus Guide Wire**

**Product Code System**

(2) Radifocus Guide Wire M without radiopaque tip marker (Standard type)

<input type="checkbox"/>	<input type="checkbox"/>	+/*	<input type="checkbox"/>							
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning									
1-2	Product name <b>RF:</b> Radifocus Guide wire M									
3	Destination <b>+/*:</b> 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/standard type, <b>S:</b> Straight/standard type									
6-7	Outer diameter of guide wire									
	Indication	18			18			25		
	Diameter (inch/mm)	0.018'' /0.46 mm (other core types)			0.020'' /0.51 mm (stiff core type)			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									
	Indication Length (cm)	05	08	12	15	18	22	26		
		50	80	120	150	180	220	260		



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Japan

**Radifocus Guide Wire**

**Product Code System**

(2) Radifocus Guide Wire M without radiopaque tip marker (Standard type)

<input type="checkbox"/>											
1	2	3	4	5	6	7	8	9	10	11	

<b>10</b>	Flexible part length in the distal tip				
	Indication	1	3	5	8
	Length (cm)	1 (short taper)	3 (normal taper)	5 (long taper)	8 (long long taper)
<b>11</b>	Languages used for labelling <b>M:</b> Multi-language				

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**Radifocus Guide Wire**

**Product Code System**

(3) Radifocus Guide Wire M with radiopaque tip marker

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>								
1	2	3	4	5	6	7	8	9	10	11	12

Position	Indication & Meaning				
<b>1-2</b>	Product name <b>RF:</b> Radifocus Guide Wire M(with radiopaque Tip Marker)				
<b>3</b>	Destination <b>*</b> : for worldwide excluding Japan				
<b>4</b>	Radiopaque marker <b>R:</b> with radiopaque gold tip marker				
<b>5</b>	Tip angle <b>A:</b> 45°, <b>B:</b> 70°				
<b>6-7</b>	Outer diameter of guide wire				
	Indication	<b>10</b>	<b>14</b>	<b>16</b>	<b>18</b>
	Diameter (inch/mm)	0.011'' /0.28 mm	0.014'' /0.36 mm	0.016'' /.041 mm	0.018'' /046 mm
<b>8-9</b>	Guide wire length <b>18</b> : 180 (cm)				
<b>10</b>	Flexible part length in the distal tip <b>8</b> : 8 (cm) (long long taper)				
<b>11</b>	Accessory supplied with the guide wire <b>T:</b> Torque device				
<b>12</b>	Languages used for labelling <b>M:</b> Multi language				



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Japan

**Radifocus Guide Wire**

**Product Code System**

(4)Radifocus Guide Wire GT

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>									
1	2	3	4	5	6	7	8	9	10	11	12	

Position	Indication & Meaning								
1-2	Product name <b>RG:</b> RADIFOCUS GUIDE WIRE GT								
3	Destination <b>*</b> : for worldwide excluding Japan								
4	Type <b>G:</b> Tip not shapeable								
5	Tip configuration: <b>A:</b> 45° angled, <b>B :</b> 70° angled, <b>C:</b> 3.0 mm J-angled, <b>E:</b> 90° angled, <b>J:</b> 1.5 mm J-angled <b>K:</b> Double-angled (110°+ 160°), <b>Q:</b> 15° angled, <b>V:</b> Double-angled (90°+ 90°), <b>W:</b> Double-angled ( 90°+ 150°), <b>X :</b> Double-angled (135°+ 150°)								
6-7	Outer diameter of guide wire								
	Indication	12	14	16					
	Diameter (inch/mm)	0.012'' /0.30 mm	0.014'' /0.36 mm	0.016'' /0.41 mm					
8-9	Guide wire length 15 : 150 (cm) , 18 : 180 (cm) , 20 : 200 (cm)								
10	Flexibility <b>S:</b> Standard, <b>F:</b> Floppy								
11	Angled tip length								
	Indication	<b>H</b>	<b>J</b>	<b>K</b>	<b>L</b>	<b>N</b>	<b>P</b>	<b>R</b>	<b>None</b> (Standard)
	Angle tip length (mm)	2	3	5	6	7	8	9	4
	For products whose angled tip length is 4 mm or is not 2, 3, 5, 6, 7, 8, 9 mm, the code number consists of 11 characters and the 11th character indicates the language for labelling.)								
12	Language for labelling <b>M:</b> Multi-language								

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