

DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**

44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

RADIFOCUS Optitorque

Angiographic Catheter

Product : Angiographic Catheter

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 60114893 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

R H +/* □ □ □ □ □ □ □ □ □ □ □ □
1 2 3 4 5 6 7 8 9 10 11 12

1) Thoracic use

Position	Meaning of indication		
1 – 2	Product type RH : Radifocus® Optitorque™		
3	Destination * : for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) + / * : for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co., Ltd)		
4	Catheter size O.D. (indication on labelling) 4 : 4 Fr. (1.40 mm) 5 : 5 Fr. (1.70 mm) 6 : 6 Fr. (2.00 mm)		
5 – 8	Indication of tip configuration : these four digits are specific for each tip shape		
	Four digits	Tip shape	Tip curve length
	AL10	AMPLATZ LEFT	Small
	AL20	AMPLATZ LEFT	Middle
	AL30	AMPLATZ LEFT	Large
	AP45	Angled Pigtail	145°
	AP55	Angled Pigtail	155°
	AP65	Angled Pigtail	165°
	APR2	Angled Pigtail	Round Type 155°
	AR10	AMPLATZ RIGHT	Small
	AR20	AMPLATZ RIGHT	Middle
	AR30	AMPLATZ RIGHT	Large
	ARJP	AMPLATZ RIGHT Type JP	Small
	ARR5	AMPLATZ MODIFIED Type NTR r5	-
	ARRC	AMPLATZ MODIFIED Type NTR	-
	BL35	Jacky Radial	3.5 cm
	BL40	Sarah Radial	4.0 cm
	BLK4	Radial BLK	4.0 cm
	BPIG	LIMA	-
	BPIM	Internal Mammary (Round tip)	-
	BPIN	Internal Mammary	-
	BPIR	Internal Mammary	-
	BPJL	Bypass Judkins Left	-
	BPJP	Internal Mammary Type JP	-
	BPJR	Bypass Judkins Right	-
	BPRB	Radial Internal Mammary Type RB	-
	BU35	BACKUP LEFT	3.5 cm
	CAS1	CASTILLO 1	Small
	CAS2	CASTILLO 2	Middle
	CL35	JUDKINS LEFT	3.5 cm
	CL40	JUDKINS LEFT	4.0 cm
	CL45	JUDKINS LEFT	4.5 cm
	CL50	JUDKINS LEFT	5.0 cm
	CL60	JUDKINS LEFT	6.0 cm
	CR35	JUDKINS RIGHT	3.5 cm
	CR40	JUDKINS RIGHT	4.0 cm
	CR45	JUDKINS RIGHT	4.5 cm
	CR50	JUDKINS RIGHT	5.0 cm

Position	Meaning of indication																																																											
	CR60	JUDKINS RIGHT										6.0 cm																																																
	FJ10	Amplatz Right Modified										-																																																
	JL35	JUDKINS LEFT										3.5 cm																																																
	JL40	JUDKINS LEFT										4.0 cm																																																
	JL50	JUDKINS LEFT										5.0 cm																																																
	JL60	JUDKINS LEFT										6.0 cm																																																
	JR35	JUDKINS RIGHT										3.5 cm																																																
	JR40	JUDKINS RIGHT										4.0 cm																																																
	JR50	JUDKINS RIGHT										5.0 cm																																																
	JR60	JUDKINS RIGHT										6.0 cm																																																
	MP25	Multipurpose										2.5cm																																																
	MP30	Multipurpose										3.0cm																																																
	MP35	Multipurpose										3.5cm																																																
	MP40	Multipurpose										4.0cm																																																
	PL15	Baby Judkins Left										1.5cm																																																
	PL20	Baby Judkins Left										2.0cm																																																
	PL25	Baby Judkins Left										2.5cm																																																
	PL30	Baby Judkins Left										3.0cm																																																
	PR15	Baby Judkins Right										1.5cm																																																
	PR20	Baby Judkins Right										2.0cm																																																
	PR25	Baby Judkins Right										2.5cm																																																
	PR30	Baby Judkins Right										3.0cm																																																
	RD30	3D-Right Modified										3.0cm																																																
	RD40	3D RC										4.0cm																																																
	SAL1	AL 1										small																																																
	SAL2	AL 2										middle																																																
	SL35	JUDKINS LEFT										3.5cm																																																
	SL40	JUDKINS LEFT										4.0cm																																																
	SL50	JL 5.0										5.0cm																																																
	SP00	Straight Pigtail										-																																																
	SP02	Straight Pigtail										Small Loop																																																
	ST01	Straight (without soft tip)										-																																																
	TIG1	TIG										4.0cm																																																
	TIG2	Radial TIG 4.5										4.5cm																																																
	TR35	Radial TIG II 3.5										3.5 cm																																																
	TR40	Radial TIG II 4.0										4.0cm																																																
	TR45	Radial TIG II 4.5										4.5 cm																																																
	TR50	Radial TIG II 5.0										5.0 cm																																																
9	Number of holes: Character: 0 1 2 3 4 5 6 7 8 9 J K L T Number: 0 1 2 3 4 5 6 7 8 9 52 20 50 4 (special side holes)																																																											
10	Catheter length : <table><tr><td>Character</td><td>4</td><td>E</td><td>5</td><td>F</td><td>6</td><td>G</td><td>7</td><td>H</td><td>8</td><td>I</td><td>9</td></tr><tr><td>Length (cm)</td><td>40</td><td>45</td><td>50</td><td>55</td><td>60</td><td>65</td><td>70</td><td>75</td><td>80</td><td>85</td><td>90</td></tr><tr><td>Character</td><td>J</td><td>0</td><td>K</td><td>1</td><td>L</td><td>2</td><td>N</td><td></td><td></td><td></td><td></td></tr><tr><td>Length (cm)</td><td>95</td><td>100</td><td>105</td><td>110</td><td>115</td><td>120</td><td>125</td><td></td><td></td><td></td><td></td></tr></table> * The maximum catheter length for the following tip shapes is 100 cm: 3D-Right Modified and 3D RC												Character	4	E	5	F	6	G	7	H	8	I	9	Length (cm)	40	45	50	55	60	65	70	75	80	85	90	Character	J	0	K	1	L	2	N					Length (cm)	95	100	105	110	115	120	125				
Character	4	E	5	F	6	G	7	H	8	I	9																																																	
Length (cm)	40	45	50	55	60	65	70	75	80	85	90																																																	
Character	J	0	K	1	L	2	N																																																					
Length (cm)	95	100	105	110	115	120	125																																																					
11	Braid cut length Q: 60 mm (For products whose braid cut length is not 60mm, the product code consists of 11 characters and the 11th character denotes the language for labeling.)																																																											
12	Languages used for the indications M: Multilanguage																																																											

	H1	Vertebral	-	None																																												
	H8	Vertebral	-	2																																												
	H9	Vertebral Bolia Mini Cath	-	None																																												
	K9	Sliding Curve	-	None																																												
	L1	BERENSTEIN	BL1	None																																												
	R5	Hinck Headhunter 1	Short tip	None																																												
	R7	MEDULLAR II	Middle	None																																												
	R8	MEDULLAR I	Small	None																																												
	R9	MEDULLAR III	Large	None																																												
7	Catheter size O.D. (indication on labelling) 4 : 4 Fr. (1.40 mm)5 : 5 Fr. (1.70 mm)																																															
8	Availability of stopcock 1 : without stopcock																																															
9 - 10	Catheter length <table border="1"><tr><td>Character</td><td>02</td><td>03</td><td>04</td><td>05</td><td>06</td><td>0G</td><td>07</td><td>0H</td><td>08</td><td>0I</td></tr><tr><td>Length (cm)</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>65</td><td>70</td><td>75</td><td>80</td><td>85</td></tr><tr><td>Character</td><td>09</td><td>0J</td><td>10</td><td>1A</td><td>11</td><td>1B</td><td>12</td><td>1C</td><td></td><td></td></tr><tr><td>Length (cm)</td><td>90</td><td>95</td><td>100</td><td>105</td><td>110</td><td>115</td><td>120</td><td>125</td><td></td><td></td></tr></table>				Character	02	03	04	05	06	0G	07	0H	08	0I	Length (cm)	20	30	40	50	60	65	70	75	80	85	Character	09	0J	10	1A	11	1B	12	1C			Length (cm)	90	95	100	105	110	115	120	125		
Character	02	03	04	05	06	0G	07	0H	08	0I																																						
Length (cm)	20	30	40	50	60	65	70	75	80	85																																						
Character	09	0J	10	1A	11	1B	12	1C																																								
Length (cm)	90	95	100	105	110	115	120	125																																								
11	Languages used for the indications M: Multilanguage																																															