

## 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 60149172 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, June 09, 2020

(place and date of issue)

  
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

Character number	Meaning of indication		
1-2	Product type RH : Radifocus® Optitorque™		
3	Destination * : for export (Manufactured by Terumo Co. Ashitaka factory) + / * : for export excluding Japan (Manufactured by Terumo Vietnam Co., Ltd)		
4	Outer diameter of catheter (indication on labelling) 4 : 4 Fr. (1.40 mm), 5 : 5 Fr. (1.70 mm), 6 : 6 Fr. (2.00 mm)		
5-8	Tip shape 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°	5.5 cm
	AP55	Angled Pigtail 155°	5.5 cm
	AP65	Angled Pigtail 165°	5.5 cm
	APR2	Angled Pigtail Round Type 155°	2.0 cm
	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	

5-8	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
	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	2.5 cm
	MP30	Multipurpose	3.0 cm
	MP35	Multipurpose	3.5 cm
	MP40	Multipurpose	4.0 cm
	PL15	Baby Judkins Left	1.5 cm
	PL20	Baby Judkins Left	2.0 cm
	PL25	Baby Judkins Left	2.5 cm
	PL30	Baby Judkins Left	3.0 cm
	PR15	Baby Judkins Right	1.5 cm
	PR20	Baby Judkins Right	2.0 cm
	PR25	Baby Judkins Right	2.5 cm
	PR30	Baby Judkins Right	3.0 cm
	RD30	3D-Right Modified	3.0 cm
	RD40	3D RC	4.0 cm
SAL1	AL 1	small	
SAL2	AL 2	middle	
SL35	JUDKINS LEFT	3.5 cm	
SL40	JUDKINS LEFT	4.0 cm	
SL50	JL 5.0	5.0 cm	

5-8	SP00	Straight Pigtail	—																																																
	SP02	Straight Pigtail	Small Loop																																																
	ST01	Straight (without soft tip)	—																																																
	TIG1	Radial TIG	4.0 cm																																																
	TIG2	Radial TIG 4.5	4.5 cm																																																
	TR35	Radial TIG II 3.5	3.5 cm																																																
	TR40	Radial TIG II 4.0	4.0 cm																																																
	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 4 6 8 Number : 0 1 2 4 6 8																																																		
10	<b>Catheter length</b> <table border="0" style="width: 100%;"> <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 colspan="4"></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 colspan="4"></td> </tr> </table> <p>* The maximum catheter length for the following tip shapes is 100 cm: 3D-Right Modified and 3D RC</p>			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																																								
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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	<b>Languages used for the indications</b> M: Multi-language																																																		

## 2) Visceral and cerebral use

Character number	Meaning of indication			
1-2	Product type RH : Radifocus® Optitorque™			
3	Destination * : for export (Manufactured by Terumo Co. Ashitaka factory) + / * : for export excluding Japan (Manufactured by Terumo Vietnam Co., Ltd)			
4	Indication of catheter use A : Visceral use, B : Cerebral use			
5-6	Tip shape Indication of tip configuration: these two digits together with digit 4 makes an unique code specific for each tip shape and number of side holes			
	Two digits	Tip shape	Tip curve length	Side holes
	<i>Visceral use</i>			
	AF	AAF	—	6
	B4	Cobra1 (C1)	Small	None
	B5	Cobra2 (C2)	Middle	None

5-6	B6	Cobra3 (C3)	Large	None	
	BI	Cobra1 (C1)	Small	1	
	C3	SHEPHERD HOOK	0.8cm	None	
	C4	SHEPHERD HOOK	1.0cm	None	
	D1	J Curve	7.0cm	None	
	D4	J Curve	Large	None	
	D5	J Curve	Middle	None	
	D6	J Curve	Small	None	
	E4	SIDEWINDER	1	None	
	E5	SIDEWINDER	2	None	
	E6	SIDEWINDER	3	None	
	EC	MESENT	—	1	
	ED	SIDEWINDER Type: S-J	1	None	
	F1	Mikaelsson (1)	—	None	
	G1	RLG	—	None	
	G3	RH	—	None	
	G4	RS	—	None	
	G9	YASHIRO TYPE	—	None	
	GF	RH Modified	—	None	
	M7	Straight	—	None	
	R9	RH CK TYPE	—	None	
	UB	UFE Type 1	19 cm	None	
	ZX	Straight	—	8	
	<i>Cerebral use</i>				
	A1	Simmons/Sidewinder 1	Sim1	None	
	A2	Simmons/Sidewinder 2	Sim2	None	
	A3	Simmons/Sidewinder 3	Sim3	None	
	B1	Hinck Headhunter 1	H1	None	
	B2	HEADHUNTER	3	None	
	B3	HEADHUNTER	4	None	
	C1	NEWTON TECHNIQUE	1	None	
	C2	NEWTON TECHNIQUE	2	None	
	C3	NEWTON TECHNIQUE	3	None	
	E1	Bentson-Hanafee-Wilson 1	JB1	None	
E2	Bentson-Hanafee-Wilson 2	JB2	None		
G1	Mani	—	None		
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		

5-6	R7	MEDULLAR II	Middle	None								
	R8	MEDULLAR I	Small	None								
	R9	MEDULLAR III	Large	None								
7	Outer diameter of catheter (indication on labelling) 4 : 4 Fr. (1.40 mm), 5 : 5 Fr. (1.70 mm)											
8	<b>Availability of stopcock</b> 1 : without stopcock											
9-10	<b>Catheter length</b>											
	Character	02	03	04	05	06	0G	07	0H	08	0I	09
	Length (cm)	20	30	40	50	60	65	70	75	80	85	90
	Character	0J	10	1A	11	1B	12	1C				
Length (cm)	95	100	105	110	115	120	125					
11	<b>Languages used for the indications</b> M: Multi-language											