

DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
Interleuvenlaan 40,
3001 Leuven, Belgium

being the manufacturer of:

RADIFOCUS® OPTITORQUE™

Product: Catheter for Angiography
(See Appendix A for related product codes)

declare that the above product of Class III is in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 11.1 (a) of the Directive, relating to the “Full Quality Assurance System” set out in Annex II, and by certification of Annex II.3 (Registration No: HD 60106290 0001) and Annex II.4 (Registration No: ID 60114894 0001), under the supervision of TÜV Rheinland LGA Products GmbH as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Leuven, 15.01.2019

(place and date of issue)



M.J. Aerts

VP Quality & Regulatory
Affairs

TERUMO EUROPE N.V.

Appendix A – Related product codes

The product code is composed of 11 digits maximum and explained as follows:

Thoracic use

1	2	3	4	5	6	7	8	9	10	11
R	H	Radifocus Optitorque								
Production site	-	Terumo Europe								
Catheter size O.D.		4	4 Fr. / 1.40 mm							
		5	5 Fr. / 1.70 mm							
		6	6 Fr. / 2.00 mm							
Indication of tip configuration								Tip Shape		
		A	L	1	0			Amplatz Left		
		A	L	2	0			Amplatz Left		
		A	L	3	0			Amplatz Left		
		A	P	4	5			Angled Pigtail 145°		
		A	P	5	5			Angled Pigtail 155°		
		A	P	6	5			Angled Pigtail 165°		
		A	P	R	2			Angled Pigtail Round Type 155°		
		A	R	1	0			Amplatz Right		
		A	R	2	0			Amplatz Right		
		A	R	3	0			Amplatz Right		
		A	R	J	P			Amplatz Right Type JP		
		A	R	R	5			Amplatz Modified Type NTR r5		
		A	R	R	C			Amplatz Modified Type NTR		
		B	L	K	4			Radial BLK		
		B	P	I	M			Internal Mammary (Round tip)		
		B	P	I	N			Internal Mammary		
		B	P	I	R			Internal Mammary (short tip)		
		B	P	J	L			Bypass Judkins Left		
		B	P	J	P			Internal Mammary type JP		
		B	P	J	R			Bypass Judkins Right		
		B	P	R	A			Internal Mammary Type RA		
		B	P	R	B			Internal Mammary Type RB		
		B	R	5	5			Hinck Headhunter 1 (short tip)		
		B	U	3	5			Backup Left		3.5 cm
		C	A	S	1			Castillo		Small
		C	A	S	2			Castillo		Middle
		C	A	S	3			Castillo		Large
		C	L	2	5			Judkins Left		2.5 cm
		C	L	3	5			Judkins Left		3.5 cm
		C	L	4	0			Judkins Left		4.0 cm
		C	L	4	5			Judkins Left		4.5 cm
		C	L	5	0			Judkins Left		5.0 cm
		C	L	6	0			Judkins Left		6.0 cm
		C	R	2	5			Judkins Right		2.5 cm
		C	R	3	5			Judkins Right		3.5 cm
		C	R	4	0			Judkins Right		4.0 cm
		C	R	4	1			Judkins Right		4.0 cm
		C	R	4	5			Judkins Right		4.5 cm
		C	R	5	0			Judkins Right		5.0 cm
		C	R	6	0			Judkins Right		6.0 cm
		H	L	4	0			Radial L-40		4.0 cm
		H	R	4	0			Radial R-40		4.0 cm
		J	L	3	5			Judkins Left (Original Shape)		3.5 cm

1	2	3	4	5	6	7	8	9	10	11
				J	L	4	0	Judkins Left (Original Shape)		4.0 cm
				J	L	5	0	Judkins Left (Original Shape)		5.0 cm
				J	R	3	5	Judkins Right (Original Shape)		3.5 cm
				J	R	4	0	Judkins Right (Original Shape)		4.0 cm
				J	R	5	0	Judkins Right (Original Shape)		5.0 cm
				J	R	6	0	Judkins Right (Original Shape)		6.0 cm
				K	T	4	0	Modified JL-4.0 Type KT		4.0 cm
				M	P	1	5	Multipurpose		1.5 cm
				M	P	2	5	Multipurpose		2.5 cm
				M	P	3	0	Multipurpose		3.0 cm
				M	P	3	1	Multipurpose (3.0 cm) Type EL GAMAL I		Small
				M	P	3	5	Multipurpose (3.5 cm)		3.5 cm
				M	P	4	0	Multipurpose (4.0 cm)		4.0 cm
				M	P	4	1	Multipurpose (4.0 cm) Type EL GAMAL II		Medium
				S	P	0	0	Straight Pigtail		-
				S	P	G	1	Straight Pigtail		Large
				S	T	0	0	Straight (with soft tip)		-
				S	T	0	1	Straight (without soft tip)		-
				S	A	L	1	Amplatz Left (short tip)		Small
				S	A	L	2	Amplatz Left (short tip)		Middle
				S	A	R	1	Amplatz Right(short tip)		Small
				S	A	R	2	Amplatz Right (short tip)		Middle
				S	L	3	5	Judkins Left (Original A Type)		3.5 cm
				S	L	4	0	Judkins Left (Original A Type)		4.0 cm
				S	R	4	0	Judkins Right (Original A Type)		4.0 cm
				T	I	G	1	Brachial Type		4.0 cm
				T	R	3	5	Radial TIG II 3.5		3.5 cm
				T	R	4	0	Radial TIG II 4.0		4.0 cm
				T	R	4	5	Radial TIG II 4.5		4.5 cm
				T	R	5	0	Radial TIG II 5.0		5.0 cm
Number of side holes								0 ~ 9	0 to 9 side holes	
Catheter length									6	60 cm
									6	65 cm
									7	70 cm
									8	80 cm
									9	90 cm
									0	100 cm
									1	110 cm
Languages used for the indications								Multi-language		M

Visceral and cerebral use

1	2	3	4	5	6	7	8	9	10	11	
R	H	RadiFocus Optitorque									
Production site		-	Terumo Europe								
Indication of catheter use & structure		A	Visceral use								
		B	Cerebral use								
Indication of tip configuration				Tip shape			Tip curve length		Side holes		
		A in position 4									
		A	2	Renal			-	None			
		B	4	Cobra 1 (C1)			Small	None			
		B	5	Cobra 2 (C2)			Middle	None			
		B	6	Cobra 3 (C3)			Large	None			
		B	P	Headhunter			9.5 cm	None			
		C	3	Shephard Hook			0.8 cm	None			
		C	4	Shephard Hook			1.0 cm	None			
		D	1	J Curve			7.0 cm	None			
		D	4	J Curve			Large	None			
		D	5	J Curve			Middle	None			
		D	6	J Curve			Small	None			
		E	4	Sidewinder			1 cm	None			
		E	5	Sidewinder			2 cm	None			
		E	6	Sidewinder			3 cm	None			
		E	D	Sidewinder Type S-J			1 cm	None			
		F	1	Mikaelsson (1)			-	None			
		P	C	BPH			19 cm	None			
		U	B	UFE			19 cm	None			
		B in position 4									
		A	1	Simmons/ Sidewinder 1			Sim 1	None			
		A	2	Simmons/ Sidewinder 2			Sim 2	None			
		A	3	Simmons/ Sidewinder 3			Sim 3	None			
		B	1	Hinck Headhunter 1			H1	None			
		B	2	Hinck Headhunter 3			H3	None			
		B	3	Headhunter			4	None			
		C	1	Newton Technique			1	None			
		C	2	Newton Technique			2	None			
		C	3	Newton Technique			3	None			
		E	1	Bentson-Hanafee-Wilson 1			JB1	None			
		E	2	Bentson-Hanafee-Wilson 2			JB2	None			
		G	1	Mani			-	None			
H	1	Vertebral			-	None					
H	8	Vertebral			-	2					
H	9	Vertebral			Bolia Minicath	None					
H	B	Vertebral (short tip)			-	None					
L	1	Berenstein			BL1	None					
R	5	Hinck Headhunter 1 (short tip)			H1	None					
R	7	Medullar II			Middle	None					
R	8	Medullar I			Small	None					
R	9	Medullar III			Large	None					
Outer diameter of catheter				4	4 Fr. / 1.40 mm						
				5	5 Fr. / 1.70 mm						
Indication of stopcock				1	Without two-way stopcock						
Catheter length				0	2	20 cm					
				0	6	65 cm					

1	2	3	4	5	6	7	8	9	10	11
								0	7	70 cm
								0	8	80 cm
								0	9	90 cm
								1	0	100 cm
								1	1	110 cm
Languages used for the indications								Multilingual		M

