

## DECLARATION OF CONFORMITY

---

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

being the manufacturer of:

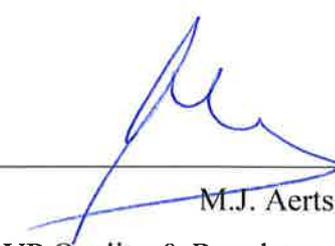
**RADIFOCUS® OPTITORQUE™**

**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	
<b>R</b>	<b>H</b>	Radifocus Optitorque									
<b>Production site</b>	-	Terumo Europe									
<b>Catheter size O.D.</b>	<b>4</b>	4 Fr. / 1.40 mm									
	<b>5</b>	5 Fr. / 1.70 mm									
	<b>6</b>	6 Fr. / 2.00 mm									
<b>Indication of tip configuration</b>											
								Tip Shape		Tip curve length	
	<b>A</b>	<b>L</b>	<b>1</b>	<b>0</b>	Amplatz Left						Small
	<b>A</b>	<b>L</b>	<b>2</b>	<b>0</b>	Amplatz Left						Middle
	<b>A</b>	<b>L</b>	<b>3</b>	<b>0</b>	Amplatz Left						Large
	<b>A</b>	<b>P</b>	<b>4</b>	<b>5</b>	Angled Pigtail 145°						5.5 cm
	<b>A</b>	<b>P</b>	<b>5</b>	<b>5</b>	Angled Pigtail 155°						5.5 cm
	<b>A</b>	<b>P</b>	<b>6</b>	<b>5</b>	Angled Pigtail 165°						5.5 cm
	<b>A</b>	<b>P</b>	<b>R</b>	<b>2</b>	Angled Pigtail Round Type 155°						2.0 cm
	<b>A</b>	<b>R</b>	<b>1</b>	<b>0</b>	Amplatz Right						Small
	<b>A</b>	<b>R</b>	<b>2</b>	<b>0</b>	Amplatz Right						Middle
	<b>A</b>	<b>R</b>	<b>3</b>	<b>0</b>	Amplatz Right						Large
	<b>A</b>	<b>R</b>	<b>J</b>	<b>P</b>	Amplatz Right Type JP						Small
	<b>A</b>	<b>R</b>	<b>R</b>	<b>5</b>	Amplatz Modified Type NTR r5						-
	<b>A</b>	<b>R</b>	<b>R</b>	<b>C</b>	Amplatz Modified Type NTR						-
	<b>B</b>	<b>L</b>	<b>K</b>	<b>4</b>	Radial BLK						-
	<b>B</b>	<b>P</b>	<b>I</b>	<b>M</b>	Internal Mammary (Round tip)						-
	<b>B</b>	<b>P</b>	<b>I</b>	<b>N</b>	Internal Mammary						-
	<b>B</b>	<b>P</b>	<b>I</b>	<b>R</b>	Internal Mammary (short tip)						-
	<b>B</b>	<b>P</b>	<b>J</b>	<b>L</b>	Bypass Judkins Left						-
	<b>B</b>	<b>P</b>	<b>J</b>	<b>P</b>	Internal Mammary type JP						-
	<b>B</b>	<b>P</b>	<b>J</b>	<b>R</b>	Bypass Judkins Right						-
	<b>B</b>	<b>P</b>	<b>R</b>	<b>A</b>	Internal Mammary Type RA						-
	<b>B</b>	<b>P</b>	<b>R</b>	<b>B</b>	Internal Mammary Type RB						-
	<b>B</b>	<b>R</b>	<b>5</b>	<b>5</b>	Hinck Headhunter 1 (short tip)						-
	<b>B</b>	<b>U</b>	<b>3</b>	<b>5</b>	Backup Left						3.5 cm
	<b>C</b>	<b>A</b>	<b>S</b>	<b>1</b>	Castillo						Small
	<b>C</b>	<b>A</b>	<b>S</b>	<b>2</b>	Castillo						Middle
	<b>C</b>	<b>A</b>	<b>S</b>	<b>3</b>	Castillo						Large
	<b>C</b>	<b>L</b>	<b>2</b>	<b>5</b>	Judkins Left						2.5 cm
	<b>C</b>	<b>L</b>	<b>3</b>	<b>5</b>	Judkins Left						3.5 cm
	<b>C</b>	<b>L</b>	<b>4</b>	<b>0</b>	Judkins Left						4.0 cm
	<b>C</b>	<b>L</b>	<b>4</b>	<b>5</b>	Judkins Left						4.5 cm
	<b>C</b>	<b>L</b>	<b>5</b>	<b>0</b>	Judkins Left						5.0 cm
	<b>C</b>	<b>L</b>	<b>6</b>	<b>0</b>	Judkins Left						6.0 cm
	<b>C</b>	<b>R</b>	<b>2</b>	<b>5</b>	Judkins Right						2.5 cm
<b>C</b>	<b>R</b>	<b>3</b>	<b>5</b>	Judkins Right						3.5 cm	
<b>C</b>	<b>R</b>	<b>4</b>	<b>0</b>	Judkins Right						4.0 cm	
<b>C</b>	<b>R</b>	<b>4</b>	<b>1</b>	Judkins Right						4.0 cm	
<b>C</b>	<b>R</b>	<b>4</b>	<b>5</b>	Judkins Right						4.5 cm	
<b>C</b>	<b>R</b>	<b>5</b>	<b>0</b>	Judkins Right						5.0 cm	
<b>C</b>	<b>R</b>	<b>6</b>	<b>0</b>	Judkins Right						6.0 cm	
<b>H</b>	<b>L</b>	<b>4</b>	<b>0</b>	Radial L-40						4.0 cm	
<b>H</b>	<b>R</b>	<b>4</b>	<b>0</b>	Radial R-40						4.0 cm	
<b>J</b>	<b>L</b>	<b>3</b>	<b>5</b>	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
<b>Number of side holes</b>								<b>0 ~ 9</b>	0 to 9 side holes	
<b>Catheter length</b>									<b>6</b>	60 cm
									<b>6</b>	65 cm
									<b>7</b>	70 cm
									<b>8</b>	80 cm
									<b>9</b>	90 cm
									<b>0</b>	100 cm
									<b>1</b>	110 cm
<b>Languages used for the indications</b>								Multi-language		<b>M</b>

*Visceral and cerebral use*

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

