

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS[®]

ANGIOGRAPHIC CATHETER

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 60114889 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 and Regulatory
Affairs

TERUMO EUROPE N.V.

Appendix A – Related product codes

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

1	2	3	4	5	6	7	8	9	10	11	
R	F	RadiFocus									
Production site		-	Terumo Europe								
Indication of catheter use & structure		D	Renal & Visceral use								
		E	Cerebral								
		F	Cardiac								
Indication of tip configuration				Tip shape					Tip curve length		Side holes
		D In position 4									
		A	1	Femoral-Visceral RENAL					-	2	
		A	2	Femoral-Visceral RENAL					-	None	
		A	4	Femoral-Visceral Cobra Kimoto Type					Small	None	
		A	7	Modified RENAL					-	None	
		A	8	Femoral-Visceral Cobra					Small	1	
		A	B	Femoral-Visceral RENAL Right (small curve)					-	None	
		A	C	Femoral-Visceral RENAL Left					-	None	
		B	1	Femoral-Visceral COBRA					Small	2	
		B	2	Femoral-Visceral COBRA					Middle	2	
		B	3	Femoral-Visceral COBRA					Large	2	
		B	4	Femoral-Visceral COBRA					Small	None	
		B	5	Femoral-Visceral COBRA					Middle	None	
		B	6	Femoral-Visceral COBRA					Large	None	
		B	7	Femoral-Visceral Cobra					Small	2	
		B	8	Femoral-Visceral Cobra					Middle	2	
		B	9	Femoral-Visceral Cobra					Large	2	
		C	1	Femoral-Visceral Shepherd Hook					0.8 cm	2	
		C	2	Femoral-Visceral Shepherd Hook					1.0 cm	2	
		C	3	Femoral-Visceral Shepherd Hook					0.8 cm	None	
		C	4	Femoral-Visceral Shepherd Hook					1.0 cm	None	
		C	6	Femoral-Visceral Shepherd Hook					1.2 cm	None	
		C	7	Femoral-Visceral Shepherd Hook					CJ1	None	
		C	8	Femoral-Visceral Shepherd Hook					CJ2	1	
		D	3	Femoral-Visceral J Curve					Small	2	
		D	4	Femoral-Visceral J-Curve					1	None	
		D	5	Femoral-Visceral J-Curve					2	None	
		D	6	Femoral-Visceral J-Curve					3	None	
		D	8	Femoral-Visceral J Curve					4 cm	None	
		E	1	Femoral-Visceral Sidewinder					1	2	
		E	2	Femoral-Visceral Sidewinder					2	2	
		E	3	Femoral-Visceral Sidewinder					3	2	
		E	4	Femoral-Visceral Sidewinder					1	None	
		E	5	Femoral-Visceral Sidewinder					2 cm	None	
		E	6	Femoral-Visceral Sidewinder					3 cm	None	
		F	1	Femoral-Visceral Mikaelsson					1	None	
		F	2	Femoral-Visceral Mikaelsson					2	None	
		F	3	Femoral-Visceral Mikaelsson					3	None	
		G	1	Femoral-Visceral RLG					-	None	
		G	2	Femoral-Visceral RDP					-	None	
H	1	Femoral-Visceral Shepherd Hook Modified					15.0 mm	1			
H	2	Femoral-Visceral Shepherd Hook Modified					17.5 mm	1			

1	2	3	4	5	6	7	8	9	10	11
Indication of tip configuration (continued)				H	3	Femoral-Visceral Shepherd Hook Modified	20.0 mm			1
				H	4	Femoral-Visceral Shepherd Hook Modified	30.0 mm			1
				L	1	Femoral-Visceral JA	1			None
				N	3	Femoral-Visceral Hook T	3			1
				N	6	Femoral-Visceral Hook R	-			1
				N	8	Femoral-Visceral Hook	AGC			None
				N	9	Femoral-Visceral Kyuudai Type	-			-
				O	1	Femoral-Visceral Hirai Type	-			None
				O	4	Femoral-Visceral Hook 10	-			None
				O	5	Femoral-Visceral Nagatomi Type	1			None
				O	6	Femoral-Visceral Nagatomi Type	2			None
				P	1	Femoral-Visceral LG	-			None
				P	4	Femoral-Visceral Yamawaki-R	-			None
				Q	1	Femoral-Visceral GT	1			None
				Q	2	Femoral-Visceral GT	1			2
				Q	7	Femoral-Visceral NCC	-			None
				S	1	Femoral-Visceral Hiramatsu	1			None
				S	7	Femoral-Visceral Shepherd Hook KT Type	-			1
				S	8	Femoral-Visceral Shepherd Hook KK Type	-			1
				T	1	Femoral-Visceral J Curve	Large			1
				T	7	Femoral-Visceral J Curve Short tip	Large			None
				V	2	Femoral-Visceral LAV	55 mm			None
E In position 4										
				A	1	Femoral-Cerebral Simmons	1			None
				A	2	Femoral-Cerebral Simmons	2			None
				A	3	Femoral-Cerebral Simmons	3			None
				A	4	Femoral-Cerebral Simmons	4			None
				B	1	Femoral-Cerebral Headhunter	1			None
				B	2	Femoral-Cerebral Headhunter	3			None
				B	3	Femoral-Cerebral Headhunter	4			None
				B	4	Femoral-Cerebral Hilal Modified Headhunter	H1H			None
				B	6	Femoral-Cerebral Hilal Modified Headhunter	H5H			None
				B	7	Femoral-Cerebral Hilal Modified Headhunter	H6H			None
				B	8	Femoral-Cerebral Hilal Modified Headhunter	H1P			None
				C	1	Femoral-Cerebral Newton Technique	1			None
				C	2	Femoral-Cerebral Newton Technique	2			None
				C	3	Femoral-Cerebral Newton Technique	3			None
				C	4	Femoral-Cerebral Newton Technique	4			None
				C	5	Femoral-Cerebral Newton Technique	5			None
				C	9	Femoral-Cerebral K Special	-			None
				D	1	Femoral-Cerebral Harwood-Nash	1			None
				E	1	Femoral-Cerebral Bentson-Hanafee-Wilson	1			None
				E	2	Femoral-Cerebral Bentson-Hanafee-Wilson	2			None
				E	3	Femoral-Cerebral Bentson-Hanafee-Wilson 3	JB3			None
				E	9	Femoral-Cerebral Kameyana	-			None
				F	1	Femoral-Cerebral Kerber	-			None
				F	8	Femoral-Cerebral Bentson-Hanafee-Wilson 2 Modified	JB2			None
				G	1	Femoral-Cerebral Mani	-			None
				H	1	Femoral-Cerebral Vertebral	-			None
				H	4	Femoral-Cerebral Vertebral	-			2
				J	1	Femoral-Cerebral Hinck	1			None
				J	2	Femoral-Cerebral Hinck	2			None
				K	1	Femoral-Cerebral Niigata Type	1			None
				K	2	Femoral-Cerebral Niigata Type	2			None

1	2	3	4	5	6	7	8	9	10	11	
Indication of tip configuration (continued)				L	1	Femoral-Cerebral Berenstein				-	None
				L	3	Femoral-Cerebral Berenstein Komonji Type				-	2
				F in position 4							
				G	1	Femoral-Ventricular Pigtail				-	6
				K	1	Femoral-Ventricular Straight				-	6
Outer diameter of catheter					5	5 Fr. / 1.70 mm					
Indication of stopcock							0	Without Two-way stopcock			
Catheter length								0	G	65 cm	
								0	7	70 cm	
								0	8	80 cm	
								0	9	90 cm	
								1	0	100 cm	
								1	1	110 cm	
Packaging indication								Multilingual		M	