DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS® GUIDE WIRE M

Product: **Guide Wire 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 60116053 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.

Digitally signed by Grabazei Alexandru
Date: 2020.09.09 09:36:34 EEST
Reason: MoldSign Signature
Location: Moldova

Appendix A – Related product codes

The product code is composed of 12 digits maximum and explained as follows:

1	2	3	4	5	6	7	8	9	10	11	12
R	F	RadiFocus									
Production site		-	Terumo Europe N.V.								
Core wire flexibility			G	Standard							
			P	Stiff							
Tip configuration				A	Angled						
				S	Straight						
Outer diameter of guide wire					1	8	0.018" / 0.46 mm				
					1	8	0.020" / 0.51 mm (only for stiff type)				
					2	5	0.025" / 0.64 mm				
					3	2	0.032" / 0.81 mm				
					3	5	0.035" / 0.89 mm				
					3	8	0.038" / 0.97 mm				
Guide wire length							0	5	50 cm		
							0	8	80 cm		
							1	2	120 cm		
							1	5	150 cm		
							1	8	180 cm		
							2	2	220 cm		
							2	6	260 cm		
							3	0	300 cm		
							4	0	400 cm		
							4	5	450 cm		
Flexible part length									1	1 cm	
									3	3 cm	
									5	5 cm	
									8	8 cm	
Languages used for indication										M	Multi-language
Special product indication: alphanumerical digit to distinguish from standard items											X