Rev. 32

PS-3038

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS® INTRODUCER II
(Transradial Kit)

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

declare that the above product of Class IIa 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), 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, 29.01.2020
(place and date of issue)

M.J. Aerts
VP Regulatory & Quality
TERUMO EUROPE N.V.

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	**T**	Radifocus Introducer II Transradial Access									
Production site		**-**	Terumo Europe N.V.								
Indication of kit compostion			**R**	Sheath, Dilator, Spring guide wire and metallic entry needle							
Size of sheath in Fr				**4**	**0**	4 Fr					
				5	**0**	5 Fr					
				6	**0**	6 Fr					
				7	**0**	7 Fr					
Dilator I.D., distal tip length (difference of Dilator / sheath assembly), and type of metallic needle							Difference in length		Dilator I.D.		Metallic entry needle
							A		25		0.018"		22G x 35 mm
							D		25		0.021"		21G x 35 mm
							G		25		0.025"		20G x 35 mm
Length of the sheath							**0**	**7**	70 mm				
							1	**0**	100 mm				
Mini spring guide wire type									**N**	No guide wire			
									P	Straight, fixed core, uncoated, distal end flexible			
Packaging										**Q**	Tray pack (Multi language)		
Special product indication: alphanumerical digit to distinguish from standard items											**X**		