

## EU DECLARATION OF CONFORMITY

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

with Single Registration Number: **BE-MF-000001434**

being the manufacturer of:

### **RADIFOCUS™ Guide Wire M**

### **Non-Vascular**

**Intended purpose:** The RADIFOCUS Guide Wire M Non-Vascular is intended to assist in the placement or exchange of devices during non-vascular procedures in endourology and for the cannulation or insertion of devices into the bile ducts and pancreatic duct.

**Basic UDI-DI:** 5413206GWMNVTY

**Related product codes:** See Appendix A

declare that the above product of **Class IIa** is in conformity with applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 52.6 of the Regulation, relating to the "Conformity assessment based on a quality management system and on assessment of technical documentation" set out in Annex IX, and by certification of Annex IX.3 (EU quality management system certificate number HZ 1594584-1), 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.

This EU declaration of conformity is issued under our sole responsibility.

Leuven , 2023-07-04

(place and date of issue)

A blue ink signature, likely of K. Verhaert, written over a horizontal line.

K. Verhaert  
VP Quality, Regulatory & Vigilance  
For and on behalf of TERUMO  
EUROPE N.V.

## Appendix A – Related product codes

- The product code is composed of 11 (or 12) digits maximum and explained as follows:

1	2	3	4	5	6	7	8	9	10	11	12
<b>N</b>	<b>V</b>	RADIFOCUS Guide Wire M Non-Vascular									
<b>Production site</b>		-	Terumo Europe N.V.								
<b>Core wire flexibility</b>		<b>G</b>	Standard type								
		<b>P</b>	Stiff type								
<b>Tip configuration</b>		<b>A</b>	Angled								
		<b>S</b>	Straight								
<b>Nominal outer diameter of guide wire</b>				<b>1</b>	<b>8</b>	0.018" / 0.46 mm (for standard type)					
				<b>1</b>	<b>8</b>	0.020" / 0.51 mm (for stiff type)					
				<b>2</b>	<b>5</b>	0.025" / 0.64 mm					
				<b>3</b>	<b>2</b>	0.032" / 0.81 mm					
				<b>3</b>	<b>5</b>	0.035" / 0.89 mm					
				<b>3</b>	<b>8</b>	0.038" / 0.97 mm					
<b>Nominal length of guide wire</b>						<b>0</b>	<b>8</b>	80 cm			
						<b>1</b>	<b>2</b>	120 cm			
						<b>1</b>	<b>5</b>	150 cm			
						<b>1</b>	<b>8</b>	180 cm			
						<b>2</b>	<b>2</b>	220 cm			
						<b>2</b>	<b>6</b>	260 cm			
						<b>3</b>	<b>0</b>	300 cm			
						<b>4</b>	<b>0</b>	400 cm			
						<b>4</b>	<b>5</b>	450 cm			
<b>Flexible tip length</b>								<b>3</b>	3 cm		
<b>Languages used for indication</b>										<b>M</b>	Multi-language
<b>Special product indication</b> (Packaging variation)										<b>1</b>	

- List of product codes

Standard type - Angled	Standard type - Straight	Stiff type - Angled	Stiff type - Straight
NV-GA18153M	NV-GS18153M	NV-PA18153M	NV-PS18453M
NV-GA25153M	NV-GS25123M	NV-PA18453M	NV-PS25453M
NV-GA32153M	NV-GS25153M	NV-PA25153M	NV-PS35083M
NV-GA32263M	NV-GS32153M	NV-PA25453M	NV-PS35153M
NV-GA32403M	NV-GS32263M	NV-PA35153M	NV-PS35153M1
NV-GA35083M	NV-GS32403M	NV-PA35183M	NV-PS35183M
NV-GA35123M	NV-GS35123M	NV-PA35263M	NV-PS35263M
NV-GA35153M	NV-GS35153M	NV-PA35403M	NV-PS35403M
NV-GA35183M	NV-GS35183M	NV-PA38153M	NV-PS38153M
NV-GA35263M	NV-GS35263M		NV-PS38183M
NV-GA35403M	NV-GS35403M		
NV-GA35453M	NV-GS35453M		
NV-GA38153M	NV-GS38153M		