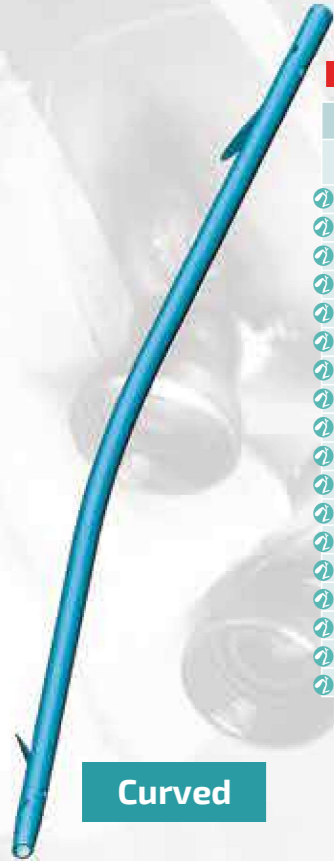


BILIARY STENT

PANCREATIC STENT

NEW



Size Table(Biliary Stent)

Stent Diameter Stent Length/ Stent Type	5F		7F		8,5F		10F		11F	
	BS	BSP	BS	BSP	BS	BSP	BS	BSP	BS	BSP
5 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
6 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
7 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
12 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
13 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
14 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
15 cm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
16 cm	x	x	✓	x	✓	x	✓	x	✓	x
17 cm	x	x	✓	x	✓	x	✓	x	✓	x
18 cm	x	x	✓	x	✓	x	✓	x	✓	x
19 cm	x	x	✓	x	✓	x	✓	x	✓	x
20 cm	x	x	✓	x	✓	x	✓	x	✓	x
21 cm	x	x	✓	x	✓	x	✓	x	✓	x
22 cm	x	x	✓	x	✓	x	✓	x	✓	x

Curved



Coding

BS	5	7	C
1	2	3	4

- 1- BS : Stent Type
- 2- 5 : Stent Diameter
- 3- 7 : Stent Length
- 4- C : Stent Model

Product Specifications

- * High fluidity
- * PTFE material with good radiopacity and nonstick surface
- * Optional metal radiopaque markers

Coding Table

Stent Type	BS BSP	Biliary Stent Biliary Stent w/markerband
Stent Diameter	5	5F (1,8 mm)
	7	7F (2,3 mm)
	8,5	8,5F (2,8 mm)
	10	10F (3,3 mm)
	11,5	11,5F (3,8 mm)
Stent Length	5	5 cm
	6	6 cm
	7	7 cm
	8	8 cm
	9	9 cm
	10	10 cm
	11	11 cm
	12	12 cm
	13	13 cm
	14	14 cm
	15	15 cm
	16	16 cm
	17	17 cm
	18	18 cm
	19	19 cm
	20	20 cm
	21	21 cm
	22	22 cm
Stent Model	C	Curved



Size Table(Pancreatic Stent)

Stent Diameter	5F	7F	10F
Stent Length/ Stent Type	PS	PS	PS
2 cm	✓	x	x
3 cm	✓	✓	✓
4 cm	✓	✓	✓
5 cm	✓	✓	✓
6 cm	✓	✓	✓
7 cm	✓	✓	✓
8 cm	✓	✓	✓
9 cm	✓	✓	✓
10 cm	✓	✓	✓
11 cm	✓	✓	✓
12 cm	✓	✓	✓
13 cm	✓	✓	✓
14 cm	✓	✓	✓
15 cm	✓	✓	✓
16 cm	x	✓	✓
17 cm	x	✓	✓
18 cm	x	✓	✓

Coding Table

Stent Type	PS	Pancreatic Stent
Stent Diameter	5	5F
	7	7F
	10	10F
Stent Length	2	2 cm
	3	3 cm
	4	4 cm
	5	5 cm
	6	6 cm
	7	7 cm
	8	8 cm
	9	9 cm
	10	10 cm
	11	11 cm
	12	12 cm
	13	13 cm
	14	14 cm
	15	15 cm
	16	16 cm
	17	17 cm
	18	18 cm
	Flap Number	S



Coding

PS	5	10	S
1	2	3	4

- 1- PS : Stent Type
- 2- 5 : Stent Diameter
- 3- 10 : Stent Length
- 4- S : Flap Number

Product Specifications

- * High fluidity
- * PTFE material with good radiopacity and nonstick surface

BILIARY STENT SET NEW

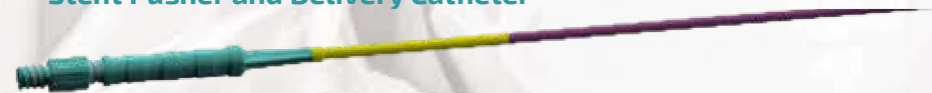
Stent Pusher



Size Table

Pusher Length	5F P	7F P
180 cm	✓	✓

Stent Pusher and Delivery Catheter



Size Table

Set Length	8.5F PG	10F PG	11.5F PG
180/210cm	✓	✓	✓

Coding Table

Stent Set Model	P PBS PG PG BS	Stent Pusher Stent Pusher and Biliary Stent Pusher and Delivery Catheter Biliary Stent Set
Stent Set Diameter	5 7 8 10 11.5	5F 7F 8,5F 10F 11,5F
Stent Set Length	18 18/21	180 cm 180/210 cm
Biliary Stent Length	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	5 cm 6 cm 7 cm 8 cm 9 cm 10 cm 11 cm 12 cm 13 cm 14 cm 15 cm 16 cm 17 cm 18 cm 19 cm 20 cm 21 cm 22 cm
Stent Model	C	Curved



Coding

PG BS 10 18/21 10 C
1 2 3 4 5

- 1- PG BS : Biliary Stent Set
- 2- 10 : Stent Diameter
- 3- 18/21 : Stent Set Length
- 4- 10 : Stent Length
- 5- C : Stent Model

Product Specifications

- * High fluidity
- * PTFE Catheter with nonstick surface
- * Radiopaque Markers

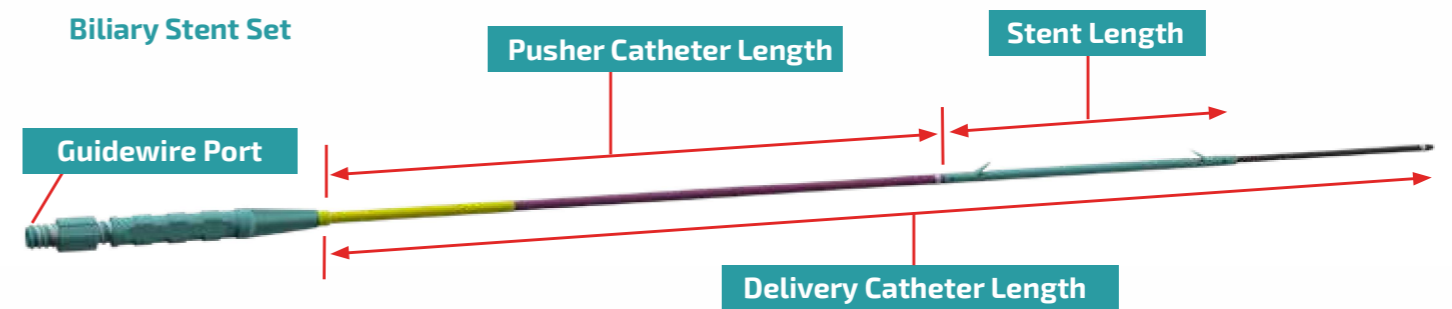
Stent Pusher and Biliary Stent



Size Table

Pusher Length	Stent Length	5F P BS	7F P BS
180 cm	5 cm	✓	✓
180 cm	6 cm	✓	✓
180 cm	7 cm	✓	✓
180 cm	8 cm	✓	✓
180 cm	9 cm	✓	✓
180 cm	10 cm	✓	✓
180 cm	11 cm	✓	✓
180 cm	12 cm	✓	✓
180 cm	13 cm	✓	✓
180 cm	14 cm	✓	✓
180 cm	15 cm	✓	✓
180 cm	16 cm	X	✓
180 cm	17 cm	X	✓
180 cm	18 cm	X	✓
180 cm	19 cm	X	✓
180 cm	20 cm	X	✓
180 cm	21 cm	X	✓
180 cm	22 cm	X	✓

Biliary Stent Set



Size Table

Set Length	Stent Length	8.5F PG BS	10F PG BS	11.5F PG BS
180/210cm	5 cm	✓	✓	✓
180/210cm	6 cm	✓	✓	✓
180/210cm	7 cm	✓	✓	✓
180/210cm	8 cm	✓	✓	✓
180/210cm	9 cm	✓	✓	✓
180/210cm	10 cm	✓	✓	✓
180/210cm	11 cm	✓	✓	✓
180/210cm	12 cm	✓	✓	✓
180/210cm	13 cm	✓	✓	✓
180/210cm	14 cm	✓	✓	✓
180/210cm	15 cm	✓	✓	✓
180/210cm	16 cm	✓	✓	✓
180/210cm	17 cm	✓	✓	✓
180/210cm	18 cm	✓	✓	✓
180/210cm	19 cm	✓	✓	✓
180/210cm	20 cm	✓	✓	✓
180/210cm	21 cm	✓	✓	✓
180/210cm	22 cm	✓	✓	✓



EC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : Technocast Otomotiv San ve Tic. A.Ş.

Company Address : Organize Sanayi Bölgesi Gazi Osman Paşa Mah. 6. Cad. No:12
Çerkezköy TEKİRDAĞ / TURKEY

Üretim Adresi : Technocast Otomotiv San ve Tic. A.Ş. Medikal Şubesi
Çerkezköy Organize San. Bölg. Gazi Osman Paşa Mah. 6. Cad.
No:26 Çerkezköy TEKİRDAĞ/ TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : Sclerotherapy Needle - Class IIa - Sterile
Pancreatic Stent - Class IIa - Sterile
Stent Pusher - Class Is - Sterile
Stent Pusher and Delivery Catheter - Class Is - Sterile
Stent Pusher and Biliary Stent - Class IIa - Sterile
Biliary Stent Set - Class IIa - Sterile

GMDN : 38825, 42701, 46689, 46689, 46689, 46689

Certificate Number : M.2021.106.14330

Report Number : MD.3157.IB

Initial Assessment Date : 05.01.2021

Registration Date : 19.03.2021

Revision Date /No : -

Expiry Date : 27.05.2024



UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.



UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr



C E R T I F I C A T E

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Technocast Otomotiv San ve Tic. A.Ş.
Company Address	: Organize Sanayi Bölgesi Gazi Osman Paşa Mah. 6. Cad. No:12 Çerkezköy TEKİRDAĞ / TURKEY
Manufacturing Site	: Technocast Otomotiv Sanayi ve Ticaret A.Ş. Medikal Şubesi Çerkezköy Organize San. Bölg. Gazi Osman Paşa Mah. 6. Cad. No:26 Çerkezköy TEKİRDAĞ / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Extraction Basket - Class IIa - Sterile - Grasping Forceps - Class IIa - Sterile - Sphincterotome - Class IIb - Sterile - Polypectomy Snare - Class IIb - Sterile - E.R.C.P Catheter - Class Is - Sterile - Stone Extraction Balloon - Class IIa - Sterile - Biliary Stent - Class IIa - Sterile
GMDN	: 37141, 37141, 58039, 38827, 16429, 46715, 10696
Certificate Number	: M.2016.106.7002
Report Number	: MD.3157.YB
Initial Assessment Date	: 27.07.2016
Registration Date	: 04.10.2016
Recertification Assessment Date	: 04.03.2020
Reissue Date / No	: 10.06.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024



UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.



UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design-examination certificate is required for placing the Class II devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76

E-mail: info@udemltd.com.tr www.udem.com.tr

Radifocus™ Guide Wire

M Non-Vascular

Description
Characteristics
Guide Wire
General specifications

Item specifications



Description

The RADIFOCUS™ Guide Wire M Non-Vascular is a standard and stiff Nitinol guidewire covered with polyurethane containing tungsten and a hydrophilic polymer coating (Mcoat™) for non-vascular procedures.

Intended to assist in the placement or exchange of devices during non-vascular procedures in endo-urology and for the cannulation or insertion of devices into the bile ducts and pancreatic duct.

Characteristics

- Rounded tip of Nitinol core combined with flexible tapered design ensure atraumatic navigation through the (non-vascular) vessels
- Nitinol core:

- Durable shape memory of super-elastic Nitinol core provides distal tip shape
- Balanced transition from tapered distal core to the more rigid proximal shaft for good crossability

Home > Medical field > Peripheral Intervention > Basicus™ Guide Wire M Gui...

Description

Characteristics

General specifications

Item specifications

- One piece construction
- Coating MCoat™:
 - Excellent durability of hydrophilic MCoat™ for sustained ease of navigation throughout the procedure
 - Terumo's MCoat™ superior lubricity combined with the most flexible distal tip ensure high trackability through any vasculature.

General specifications

Core material	Nitinol
Radiopaque jacket	Polyurethane layer containing tungsten
Hydrophilic coating	MCoat™
Guidewire diameters	0.018" (0.46 mm + 0.02 mm)* / 0.020" (0.51 mm + 0.01 mm)* / 0.025" (0.64 mm + 0.00 mm)* / 0.032" (0.81 mm + 0.00 mm)* / 0.035" (0.89 mm + 0.01 mm)* / 0.038" (0.97 mm + 0.02 mm)*
Guidewire lengths	80 cm / 120 cm / 150 cm / 180 cm / 260 cm / 400 cm / 450 cm
Distal flexible length	3 cm
Distal curves	Straight / Angled
Units per box	5

* Nominal OD + upper tolerance, reflecting Maximal OD.

Item specifications

Description

Characteristics

General specifications

Item specifications

Product code	Wire type	Outer diameter	Length	Flexible tip length	Tip shape
NV-GS18153M	Standard	0.018" (0.46 mm + 0.02 mm)*	150 cm	3 cm	Straight
NV-GA18153M	Standard	0.018" (0.46 mm + 0.02 mm)*	150 cm	3 cm	45° Angled
NV-PA18153M	Stiff	0.020" (0.51 mm + 0.01 mm)*	150 cm	3 cm	45° Angled
NV-PS18453M	Stiff	0.020" (0.51 mm + 0.01 mm)*	450 cm	3 cm	Straight
NV-PA18453M	Stiff	0.020" (0.51 mm + 0.01 mm)*	450 cm	3 cm	45° Angled
NV-GS25153M	Standard	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	Straight
NV-GA25153M	Standard	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	45° Angled
NV-PA25153M	Stiff	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	45° Angled
NV-PS25453M	Stiff	0.025" (0.64 mm + 0.00 mm)*	450 cm	3 cm	Straight
NV-PA25453M	Stiff	0.025" (0.64 mm + 0.00 mm)*	450 cm	3 cm	45° Angled
NV-GS32153M	Standard	0.032" (0.81 mm + 0.00 mm)*	150 cm	3 cm	Straight
NV-GA32153M	Standard	0.032" (0.81 mm + 0.00 mm)*	150 cm	3 cm	45° Angled
NV-GS32263M	Standard	0.032" (0.81 mm + 0.00 mm)*	260 cm	3 cm	Straight
NV-GA32263M	Standard	0.032" (0.81 mm + 0.00 mm)*	260 cm	3 cm	45° Angled
NV-GS32403M	Standard	0.032" (0.81 mm + 0.00 mm)*	400 cm	3 cm	Straight
NV-GA32403M	Standard	0.032" (0.81 mm + 0.00 mm)*	400 cm	3 cm	45° Angled

Description

Characteristics

General specifications

Item specifications

	Standard	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	45° Angled
NV-GA35083M	Standard	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	45° Angled
NV-PS35083M	Stiff	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	Straight
NV-GS35123M	Standard	0.035" (0.89 mm + 0.01 mm)*	120 cm	3 cm	Straight
NV-GA35123M	Standard	0.035" (0.89 mm + 0.01 mm)*	120 cm	3 cm	45° Angled
NV-GS35153M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	Straight
NV-GA35153M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	45° Angled
NV-PS35153M	Stiff	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	Straight
NV-PA35153M	Stiff	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	45° Angled
NV-GS35183M	Standard	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	Straight
NV-PS35183M	Stiff	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	Straight
NV-GS35263M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	Straight
NV-GA35263M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	45° Angled
NV-PA35263M	Stiff	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	45° Angled
NV-GS35403M	Standard	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	Straight
NV-GA35403M	Standard	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	45° Angled
NV-PS35403M	Stiff	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	Straight
NV-PA35403M	Stiff	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	45° Angled
NV-GS35453M	Standard	0.035" (0.89 mm + 0.01 mm)*	450 cm	3 cm	Straight
NV-GA35453M	Standard	0.035" (0.89 mm + 0.01 mm)*	450 cm	3 cm	45° Angled
NV-GS38153M	Standard	0.038" (0.97 mm + 0.02 mm)*	150 cm	3 cm	Straight
NV-PS38153M	Stiff	0.038" (0.97 mm + 0.02 mm)*	150 cm	3 cm	Straight
NV-PS38183M	Stiff	0.038" (0.97 mm + 0.02 mm)*	180 cm	3 cm	Straight

Products ▾

Events

Learning

Q Search

Home > Medical field > Peripheral Intervention > **Nominal OD + upper tolerance reflecting Maximal OD.**

Description

Characteristics

General specifications

Item specifications

Do you need more info about this product?

Our sales representatives are here for you.

Contact us

Related products



Home > Medical field > Peripheral Intervention > Radifocus™ Guide Wire M Gui...

Description

Characteristics

General specifications

TR Band™

Radial Artery Compression Device

Item specifications

FemoSeal™

Vascular Closure System

Progreat™

Micro Catheter System

NaviCross™

Support Ca

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 Safety and performance

EU DECLARATION OF CONFORMITY

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)



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
N	V	RADIFOCUS Guide Wire M Non-Vascular									
Production site		-	Terumo Europe N.V.								
Core wire flexibility		G	Standard type								
		P	Stiff type								
Tip configuration		A	Angled								
		S	Straight								
Nominal outer diameter of guide wire				1	8	0.018" / 0.46 mm (for standard type)					
				1	8	0.020" / 0.51 mm (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					
Nominal length of guide wire						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			
Flexible tip length						4	5	450 cm			
						3	3 cm				
Languages used for indication										M	Multi-language
Special product indication (Packaging variation)										1	

- 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		

EU Certificate

Quality Management System

**REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I,
Section 2 and 3 and Chapter III**



Registration No.: HZ 1594584-1

Manufacturer: **TERUMO EUROPE N.V.**
Interleuvenlaan 40
3001 Leuven
Belgium

EUDAMED Single
Registration No.: BE-MF-000001434

Products: Products of class IIa:

A010101 HYPODERMIC NEEDLES
A020199 SYRINGES - OTHERS
A010102 BUTTERFLY NEEDLES
U0601 UROLOGICAL GUIDEWIRES, HYDROPHILIC
G0399 DIGESTIVE ENDOSCOPY DEVICES – OTHER
C0504 ARTERIAL INTRODUCTION SETS
A010599 OPHTHALMOLOGY INJECTION NEEDLES AND KITS - OTHER

Authorised
representative(s): N/A

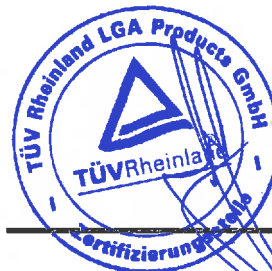
The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 1142544-10

Effective date: 2023-06-20

Expiry date: 2026-12-31

Issue date: 2023-06-20



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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I,
Section 2 and 3 and Chapter III

Registration No.: HZ 1594584-1

Manufacturer: **TERUMO EUROPE N.V.**
Interleuvenlaan 40
3001 Leuven
Belgium



Certificate history		
Revision:	Description:	Issue date:
1	First Issuance	2022-02-11
2	Update to include addition of 4 EMDN Codes to Products of Class IIa: U0601, G0399, C0504 and A010599 Note: Addition of U0601, G0399, C0504 codes per report no.: 3350367-530; and addition of A010599 code per report no.: 1142544-10	2023-06-20

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