

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 3 din 13.10.2023

Solicitantul **FCPC „DataControl” S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicită înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Product: Guide Wire for Angiography

Model: RADIFOCUS Guide Wire M

RF-GA18053M	RF*GA18183M	RF-GA25183M	RF-GS32153M	RF-GS35123M
RF*GA18153M	RF-GA18183M	RF*GA25183M	RF-GA32153M	RF-GA35123M
RF-GA18153M	RF-GS18183M	RF-GS25183M	RF-GS32183M	RF-GS35151M
RF*GS18153M	RF-GA25053M	RF-GS32123M	RF-GA32183M	RF+GS35153M
RF-GS18153M	RF-GA25123M	RF-GA32123M	RF-GA35053M	RF-GS35155M
RF-GS35158M	RF*GR35183M	RF+GA35183M	RF-GA38151M	RF-GA18263M
RF-GA35151M	RF*GB35153M	RF*GE35185M	RF+GA38153M	RF-GS18263M
RF+GA35153M	RF-GS35181M	RF*GE35188M	RF-GS38183M	RF-GS25263M
RF-GA35155M	RF-GS35183M	RF-GS38151M	RF-GA38183M	RF-GA25263M
RF-GA35158M	RF-GA35181M	RF-GS38153M	RF-GA18223M	RF-GS32263M
RF-GA32263M	RF-GA35261M	RF-PA18263M	RF-PS35303M	NV-GS32403M
RF-GS35223M	RF-GA35303M	RF-PS25263M	RF-PA35303M	NV-GA32403M
RF-GA35223M	RF-GA38223M	RF-PA25263M	RF-PA38263M	NV-PS18453M
RF-GS35261M	RF-GS38263M	RF-PS35263M	RF-PA38303M	NV-PA18453M
RF-GS35263M	RF-GA38263M	RF-PA35263M	RF-PS38303M	NV-PS25453M
				NV-PA25453M

Se anexează următoarele acte:

1. Declarație de Conformitate CE
2. Certificatul de Conformitate CE
3. Actul prin care producătorul își desemnează reprezentantul
4. Declarație pe propria răspundere.

Data **13.10.2023**

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către
Agenția Medicamentului
și Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul F.C.P.C. "DataControl" S.R.L., cu sediul în mun. Chișinău, str. N. Testemițanu 17/6, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Product: Guide Wire for Angiography

Model: RADIFOCUS Guide Wire M

RF-GA18053M	RF*GA18183M	RF-GA25183M	RF-GS32153M	RF-GS35123M
RF*GA18153M	RF-GA18183M	RF*GA25183M	RF-GA32153M	RF-GA35123M
RF-GA18153M	RF-GS18183M	RF-GS25183M	RF-GS32183M	RF-GS35151M
RF*GS18153M	RF-GA25053M	RF-GS32123M	RF-GA32183M	RF+GS35153M
RF-GS18153M	RF-GA25123M	RF-GA32123M	RF-GA35053M	RF-GS35155M
RF-GS35158M	RF*GR35183M	RF+GA35183M	RF-GA38151M	RF-GA18263M
RF-GA35151M	RF*GB35153M	RF*GE35185M	RF+GA38153M	RF-GS18263M
RF+GA35153M	RF-GS35181M	RF*GE35188M	RF-GS38183M	RF-GS25263M
RF-GA35155M	RF-GS35183M	RF-GS38151M	RF-GA38183M	RF-GA25263M
RF-GA35158M	RF-GA35181M	RF-GS38153M	RF-GA18223M	RF-GS32263M
RF-GA32263M	RF-GA35261M	RF-PA18263M	RF-PS35303M	NV-GS32403M
RF-GS35223M	RF-GA35303M	RF-PS25263M	RF-PA35303M	NV-GA32403M
RF-GA35223M	RF-GA38223M	RF-PA25263M	RF-PA38263M	NV-PS18453M
RF-GS35261M	RF-GS38263M	RF-PS35263M	RF-PA38303M	NV-PA18453M
RF-GS35263M	RF-GA38263M	RF-PA35263M	RF-PS38303M	NV-PS25453M
				NV-PA25453M

Sunt autentice și corespund realității

Alexandru Grabazei, director

Semnătura _____

Data: 13.10.2023



**Terumo Europe NV
Emerging Market Division**

Researchpark Haasrode 1520
Interleuvenlaan 40
3001 Leuven, Belgium
Tel.: +32 16 38 13 08
Fax: +32 16 38 16 01

www.terumo-europe.com

To: Whom It May Concern

Ref: 2023/007/IS/MI

Leuven, January 18, 2023

Letter of Authorization

We, begin company-manufacturer **Terumo Europe N.V. (Belgium)**;
and being the European Authorized representative of company-manufacturer **Terumo Corporation, Terumo Medical Corporation, Terumo Clinical Supply and Terumo Medical Products (Hangzhou)**;
and being the appointed distributor for products from the company-manufacturer **PendraCare, MicroVention Europe, MicroVention Inc and Kaneka Corporation**;

hereby appoint following company (hereinafter - "Company"):

FCPC "DataControl" SRL
20 Melestiu Street, MD-2001,
Chisinau, Republic of Moldova,

to be our official representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc. of following medical products and devices manufactured and/or distributed by us:

Accuforce PTCA dilatation catheter (RX)
Angio-Seal VIP Vascular Closure Device
Azur Detachment Controller
Azur Peripheral Coil System
Climber Guiding Catheter
Croserio RX PTA Balloon Dilatation Catheter
Crosstella OTW PTA Balloon Dilatation Catheter
Destination Guiding Sheath (Terumo Corporation and Terumo Medical Corporation)
Eliminate Aspiration catheter
FemoSeal Vascular Closure System
Finecross MG Coronary Micro-Guide catheter
Glidesheath Slender Hydrophilic Coated Introducer Sheath
Heartrail II Guiding Catheter
HydroPearl Compressible Microspheres for Embolisation
LifePearl Drug-elutable microspheres for embolisation
Metacross® OTW PTA Balloon Dilatation Catheter
Metacross® RX PTA Balloon Dilatation Catheter
Navicross Support Catheter
Occlusafe Temporary Occlusion Balloon Catheter
Outlook Angiographic Catheter
Progreat Micro Catheter System (Terumo Corporation and Terumo Clinical Supply)
Radifocus Glidecath Angiographic Catheter (Terumo Corporation and Terumo Europe)

Radifocus Guide Wire GT with Gold Coil
Radifocus Guide Wire M (Terumo Corporation and Terumo Europe)
Radifocus Guide Wire M Non-Vascular
RADIFOCUS® Glidewire Advantage™
RADIFOCUS® Glidewire Advantage™ Track
Radifocus Obturator
Radifocus Torque Device (Terumo Corporation and Terumo Medical Products (Hangzhou))
Radifocus Vessel Dilator
Radifocus OPTITORQUE Angiographic Catheter (Terumo Corporation and Terumo Europe)
Radifocus Introducer II (Transradial Kit)
Radifocus Introducer II
Roadsaver Carotid Artery Stent
Runthrough® NS Extension Wire PTCA Guide Wire
Runthrough® NS PTCA Guide Wire
Ryujin Plus PTCA dilatation catheter (RX)
Senri® PTA Balloon Dilatation catheter
Tercross® PTA Dilatation Catheter (OTW)
Ryurei PTCA Dilatation Catheter
TR Band Radial Artery Haemostasis Band
Ultimaster Sirolimus eluting coronary stent system
Ultimaster Tansei Sirolimus eluting coronary stent system
Ultimaster Nagomi Sirolimus eluting coronary stent system


Hereby the Company is authorized to ensure that state registration (re-registration) of the abovementioned products is obtained and maintained in accordance with the legislation of Republic of Moldova.

For this purpose, the company can perform all acts, including but not limited: to submit, confirm, receive all necessary documents, including registration certificates, to reply to inquiries, questions or other communications from authorized institutions, after consultation with Regulatory department of Terumo Europe N.V, to conduct any field actions which may be necessary, in accordance with legislation of Republic of Moldova.

Registration certificates must be issued in the name of Terumo Europe N.V.

This authorization letter is valid for a period of 12 /twelve/ months from the date of issue, unless revoked earlier by Terumo Europe N.V.

For and behalf of Terumo Europe N.V.:


Valérie Boydens

Director Regulatory Affairs
Terumo Europe NV

TERUMO
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 LEUVEN, BELG

EC Design-Examination Certificate
Directive 93/42/EEC Annex II, Section 4
Medical Devices

Registration No.: ID 60156558 0001

Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Product

Identification: Radifocus Guide Wire
(see attachment for products included)
Replaces Certificate, Registration No.: ID 60116055 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2024-05-26

Effective Date: 2021-05-14

Date: 2021-05-14

Notified Body



Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product code system

(1) Radifocus Guide Wire M without radiopaque tip marker

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning
1-2	Product name RF: Radifocus Guide Wire M (Non-Shapeable Type) RE: Radifocus Guide Wire M(Shapeable Type)
3	Destination: *: for worldwide excluding Japan
4	Core wire flexibility G: Standard, H: Half stiff, P: Stiff

Date: 2021-05-14



Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Position	Indication & Meaning									
5	Tip configuration A: Angled/standard type, B: 3mm J-angled/standard type, C: 6mm J-angled/standard type, E: Double-angled/standard type, K: Angled/Shapeable type L: Straight/Shapeable type N: 2mm J-angled/standard type, R: 1.5mm J-angled/standard type S: Straight/standard type, F: Angled/High Flex type J: Straight/High Flex Type V: 2mm J-angled/Super Flex type									
6-7	Outer diameter of guide wire Character 18 Diameter in Stiff core type: 0.020" / 0.51 mm inch/mm Other core types: 0.018" / 0.46 mm Character 25 32 35 38 0.025" / 0.032" / 0.035" / 0.038" / 0.64 mm 0.81 mm 0.89 mm 0.97 mm									
8-9	Guide wire length									
	Indication	05	07	08	12	15	18	20	22	26
	Length (cm)	50	70	80	120	150	180	200	220	260
	Indication	30	35	40	45					
	Length (cm)	300	350	400	450					
10	Flexible part length in the distal tip									
	Indication	1	3	5	8					
	Length (cm)	1 (short taper)	3 (normal taper)	5 (long taper)	8 (long long taper)					
11	Languages used for labelling M: Multi-language									

Date: 2021-05-14



Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product Code System

(2) Radifocus Guide Wire M without radiopaque tip marker (Standard type)

<input type="checkbox"/>	<input type="checkbox"/>	+/*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning									
1-2	Product name RF: Radifocus Guide wire M									
3	Destination +/*: for worldwide excluding Japan									
4	Core wire flexibility G: Standard H: Half Stiff P: Stiff									
5	Tip configuration A: Angled/standard type, S: Straight/standard type									
6-7	Outer diameter of guide wire									
	Indication	18			18			25		
	Diameter (inch/mm)	0.018'' /0.46 mm (other core types)			0.020'' /0.51 mm (stiff core type)			0.025'' /0.64 mm		
		32			35			38		
		0.032'' /0.81 mm			0.035'' /0.89 mm			0.038'' /0.97 mm		
8-9	Guide wire length									
	Indication Length (cm)	05	08	12	15	18	22	26		
		50	80	120	150	180	220	260		

Date: 2021-05-14



Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product Code System

(2) Radifocus Guide Wire M without radiopaque tip marker (Standard type)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11	

10	Flexible part length in the distal tip				
	Indication	1	3	5	8
	Length (cm)	1 (short taper)	3 (normal taper)	5 (long taper)	8 (long long taper)
11	Languages used for labelling M: Multi-language				

Date: 2021-05-14



Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product Code System

(3) Radifocus Guide Wire M with radiopaque tip marker

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11	12

Position	Indication & Meaning				
1-2	Product name RF: Radifocus Guide Wire M(with radiopaque Tip Marker)				
3	Destination * : for worldwide excluding Japan				
4	Radiopaque marker R: with radiopaque gold tip marker				
5	Tip angle A: 45°, B: 70°				
6-7	Outer diameter of guide wire				
	Indication	10	14	16	18
	Diameter (inch/mm)	0.011'' /0.28 mm	0.014'' /0.36 mm	0.016'' /.041 mm	0.018'' /046 mm
8-9	Guide wire length 18 : 180 (cm)				
10	Flexible part length in the distal tip 8 : 8 (cm) (long long taper)				
11	Accessory supplied with the guide wire T: Torque device				
12	Languages used for labelling M: Multi language				



Date: 2021-05-14

Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product Code System

(4)Radifocus Guide Wire GT

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11	12	

Position	Indication & Meaning								
1-2	Product name RG: RADIFOCUS GUIDE WIRE GT								
3	Destination * : for worldwide excluding Japan								
4	Type G: Tip not shapeable								
5	Tip configuration: A: 45° angled, B : 70° angled, C: 3.0 mm J-angled, E: 90° angled, J: 1.5 mm J-angled K: Double-angled (110°+ 160°), Q: 15° angled, V: Double-angled (90°+ 90°), W: Double-angled (90°+ 150°), X : Double-angled (135°+ 150°)								
6-7	Outer diameter of guide wire								
	Indication	12	14	16					
	Diameter (inch/mm)	0.012'' /0.30 mm	0.014'' /0.36 mm	0.016'' /0.41 mm					
8-9	Guide wire length 15 : 150 (cm) , 18 : 180 (cm) , 20 : 200 (cm)								
10	Flexibility S: Standard, F: Floppy								
11	Angled tip length								
	Indication	H	J	K	L	N	P	R	None (Standard)
	Angle tip length (mm)	2	3	5	6	7	8	9	4
	For products whose angled tip length is 4 mm or is not 2, 3, 5, 6, 7, 8, 9 mm, the code number consists of 11 characters and the 11th character indicates the language for labelling.)								
12	Language for labelling M: Multi-language								

Date: 2021-05-14



Dipl.-Ing. S. Pane

EC Design-Examination Certificate
Directive 93/42/EEC Annex II, Section 4
Medical Devices

Registration No.: ID 60156558 0001

Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Product

Identification: Radifocus Guide Wire
(see attachment for products included)
Replaces Certificate, Registration No.: ID 60116055 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2024-05-26

Effective Date: 2021-05-14

Date: 2021-05-14

Notified Body



Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product code system

(1) Radifocus Guide Wire M without radiopaque tip marker

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning
1-2	Product name RF: Radifocus Guide Wire M (Non-Shapeable Type) RE: Radifocus Guide Wire M(Shapeable Type)
3	Destination: *: for worldwide excluding Japan
4	Core wire flexibility G: Standard, H: Half stiff, P: Stiff

Date: 2021-05-14



Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Position	Indication & Meaning									
5	Tip configuration A: Angled/standard type, B: 3mm J-angled/standard type, C: 6mm J-angled/standard type, E: Double-angled/standard type, K: Angled/Shapeable type L: Straight/Shapeable type N: 2mm J-angled/standard type, R: 1.5mm J-angled/standard type S: Straight/standard type, F: Angled/High Flex type J: Straight/High Flex Type V: 2mm J-angled/Super Flex type									
6-7	Outer diameter of guide wire Character 18 Diameter in Stiff core type: 0.020" / 0.51 mm inch/mm Other core types: 0.018" / 0.46 mm Character 25 32 35 38 0.025" / 0.032" / 0.035" / 0.038" / 0.64 mm 0.81 mm 0.89 mm 0.97 mm									
8-9	Guide wire length									
	Indication	05	07	08	12	15	18	20	22	26
	Length (cm)	50	70	80	120	150	180	200	220	260
	Indication	30	35	40	45					
	Length (cm)	300	350	400	450					
10	Flexible part length in the distal tip									
	Indication	1	3	5	8					
	Length (cm)	1 (short taper)	3 (normal taper)	5 (long taper)	8 (long long taper)					
11	Languages used for labelling M: Multi-language									

Date: 2021-05-14



Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product Code System

(2) Radifocus Guide Wire M without radiopaque tip marker (Standard type)

<input type="checkbox"/>	<input type="checkbox"/>	+/*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11

Position	Indication & Meaning									
1-2	Product name RF: Radifocus Guide wire M									
3	Destination +/*: for worldwide excluding Japan									
4	Core wire flexibility G: Standard H: Half Stiff P: Stiff									
5	Tip configuration A: Angled/standard type, S: Straight/standard type									
6-7	Outer diameter of guide wire									
	Indication	18			18			25		
	Diameter (inch/mm)	0.018'' /0.46 mm (other core types)			0.020'' /0.51 mm (stiff core type)			0.025'' /0.64 mm		
		32			35			38		
		0.032'' /0.81 mm			0.035'' /0.89 mm			0.038'' /0.97 mm		
8-9	Guide wire length									
	Indication Length (cm)	05	08	12	15	18	22	26		
		50	80	120	150	180	220	260		

Date: 2021-05-14



Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product Code System

(2) Radifocus Guide Wire M without radiopaque tip marker (Standard type)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11	

10	Flexible part length in the distal tip				
	Indication	1	3	5	8
	Length (cm)	1 (short taper)	3 (normal taper)	5 (long taper)	8 (long long taper)
11	Languages used for labelling M: Multi-language				

Date: 2021-05-14



Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product Code System

(3) Radifocus Guide Wire M with radiopaque tip marker

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11	12

Position	Indication & Meaning				
1-2	Product name RF: Radifocus Guide Wire M(with radiopaque Tip Marker)				
3	Destination * : for worldwide excluding Japan				
4	Radiopaque marker R: with radiopaque gold tip marker				
5	Tip angle A: 45°, B: 70°				
6-7	Outer diameter of guide wire				
	Indication	10	14	16	18
	Diameter (inch/mm)	0.011'' /0.28 mm	0.014'' /0.36 mm	0.016'' /.041 mm	0.018'' /046 mm
8-9	Guide wire length 18 : 180 (cm)				
10	Flexible part length in the distal tip 8 : 8 (cm) (long long taper)				
11	Accessory supplied with the guide wire T: Torque device				
12	Languages used for labelling M: Multi language				



Date: 2021-05-14

Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156558 0001
Report No.: 21262067 005

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Radifocus Guide Wire

Product Code System

(4)Radifocus Guide Wire GT

<input type="checkbox"/>	<input type="checkbox"/>	*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11	12	

Position	Indication & Meaning											
1-2	Product name RG: RADIFOCUS GUIDE WIRE GT											
3	Destination * : for worldwide excluding Japan											
4	Type G: Tip not shapeable											
5	Tip configuration: A: 45° angled, B : 70° angled, C: 3.0 mm J-angled, E: 90° angled, J: 1.5 mm J-angled K: Double-angled (110°+ 160°), Q: 15° angled, V: Double-angled (90°+ 90°), W: Double-angled (90°+ 150°), X : Double-angled (135°+ 150°)											
6-7	Outer diameter of guide wire											
	Indication	12	14	16								
	Diameter (inch/mm)	0.012'' /0.30 mm	0.014'' /0.36 mm	0.016'' /0.41 mm								
8-9	Guide wire length 15 : 150 (cm) , 18 : 180 (cm) , 20 : 200 (cm)											
10	Flexibility S: Standard, F: Floppy											
11	Angled tip length											
	Indication	H	J	K	L	N	P	R	None (Standard)			
	Angle tip length (mm)	2	3	5	6	7	8	9	4			
	For products whose angled tip length is 4 mm or is not 2, 3, 5, 6, 7, 8, 9 mm, the code number consists of 11 characters and the 11th character indicates the language for labelling.)											
12	Language for labelling M: Multi-language											

Date: 2021-05-14



Dipl.-Ing. S. Pane

EC Design-Examination Certificate
Directive 93/42/EEC Annex II, Section 4
Medical Devices

Registration No.: ID 60156557 0001

Report No.: 21262066 005

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

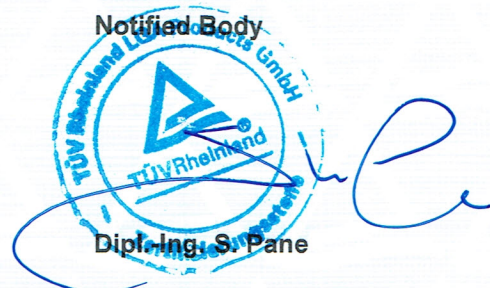
Product Identification: Radifocus Guide Wire M
(see attachment for products included)
Replaces Certificate, Registration No.: ID 60116053 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2024-05-26

Effective Date: 2021-05-14

Date: 2021-05-14

Notified Body

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** ID 60156557 0001
Report No.: 21262066 005

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
BELGIUM

Scope: Radifocus Guide Wire M

Product Code System

Radifocus Guide Wire M

R	F	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	11	12	

Position	Indication & Meaning															
1 - 2	Product group: RF : Radifocus															
3	Manufacturing site: -: TERUMO Europe N.V.															
4	Core wire flexibility: G : Standard P : Stiff															
5	Tip configuration: A : Angled S : Straight															
6-7	Outer diameter of guide wire															
	Indication	18			25			32			35			38		
	Diameter (inch)	0,018" (0,020")*			0,025"			0,032"			0,035"			0,038"		
	Diameter (mm)	0,46 mm (0,51 mm)*			0,64 mm			0,81 mm			0,89 mm			0,97 mm		
* for stiff-core type																
8-9	Guide wire length:															
	Indication:	05	08	12	15	18	22	26	30	40	45					
	Length (cm)	50	80	120	150	180	220	260	300	400	450					
10	Flexible part length:															
	Indication:	1			3			5			8					
	Length (cm)	1			3			5			8					
11	Languages used for indication: M : Multi-language															
12	Special product indication: alphanumerical digit to distinguish from standard items															

Date : 2021-05-14



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145252 0001

Report No.: 12031336 018

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo
151-0072 Japan

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC 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, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-23

Date: 2019-12-23



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60145252 0001
Report No.: 12031336 023

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

Notified Body


M.Sc. M. Aihara



Date: 2020-10-23

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60145252 0001
Report No.: 12031336 023

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Products included:

- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer
- Portable insulin infusion pump
- Portable insulin infusion administration set

Notified Body



Date: 2020-10-23

M. Aihara
M.Sc. M. Aihara

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145252 0001

Report No.: 12031336 018

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo
151-0072 Japan

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC 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, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-23

Date: 2019-12-23



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60145252 0001
Report No.: 12031336 023

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

Notified Body

Date: 2020-10-23

M. Aihara
M.Sc. M. Aihara



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60145252 0001
Report No.: 12031336 023

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Products included:

- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer
- Portable insulin infusion pump
- Portable insulin infusion administration set

Notified Body

Date: 2020-10-23

M. Aihara
M.Sc. M. Aihara



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60134707 0001

Report No.: 21240046 017

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

Products: (see attachment for products and additional sites included)

Replaces Certificate, Registration No.: HD 60106290 0001


Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC 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, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-04-21

Date: 2020-04-21

Notified Body


Dipl.-Ing. (FH) D. Wiedemuth



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: HD 60134707 0001
Report No.: 21240046 017

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

Products included:

- Syringes
- Needles
- Administration sets
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires
- Introducer for vascular access
- Angiographic Catheters
- Guidewire for Angiography

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles

Date: 2020-04-21

Notified Body



D. Wiedemuth
Dipl.-Ing. (FH) D. Wiedemuth

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: HD 60134707 0001
Report No.: 21240046 017

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

additional sites included:

Terumo Europe N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium

Terumo Europe UK
3 Unity Grove, Knowsley Business Park South
Knowsley, Merseyside L34 9GT, United Kingdom

Date: 2020-04-21

Notified Body



D. Wiedemuth
Dipl.-Ing. (FH) D. Wiedemuth

DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

RADIFOCUS Guide Wire M


Product : Catheter Guide Wire

declare that the above products of **Class III** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 (Registration No.: HD 60145252 0001), and Annex II, Section 4 (Registration No.: ID 60156558 0001) under the supervision of TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, June 3, 2021
(place and date of issue)


Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

RADIFOCUS GUIDEWIRE M Product code system

- 1) Without radiopaque tip marker
Standard type

R F * □ □ □ □ □ □ □ □ □ □
1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation						
1-2	Product name	RADIFOCUS GUIDE WIRE M					
3	Destination	* : for export					
4	Core wire flexibility	G : Standard H : Half stiff P : Stiff					
5	Tip configuration	A : Angled B : J-angled (3mm) C : J-angled (6mm) E : Double-angled N : J-angled (2mm) R : J-angled (1.5mm) S : Straight					
6-7	Outer diameter of guide wire	18			25		
		stiff-core type: 0.020" other core types: 0.018"					
		32		35		38	
		0.032"		0.035"		0.038"	
8-9	Guide wire length	05	07	08	12	15	18
		50 cm	70 cm	80 cm	120 cm	150 cm	180 cm
		22	26	30	35	40	45
		220 cm	260cm	300cm	350cm	400 cm	450 cm
10	Flexible part length in the distal tip	1 : 1cm (short taper) 3 : 3cm (normal taper) 5 : 5cm (long taper) 8 : 8cm (long long taper)					
11	Languages used for the indications	M : Multilanguage					

High Flex Type

 R F * □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation									
1-2	Product name	RADIFOCUS GUIDE WIRE M								
3	Destination	*: for export								
4	Core wire flexibility	G : Standard H : Half stiff								
5	Tip configuration	J : Straight F : Angled								
6-7	Outer diameter of guide wire	18	25	32	35	38				
		0.018"	0.025"	0.032"	0.035"	0.038"				
8-9	Guide wire length	12	15	18	22	26	30	40	45	
		120cm	150cm	180cm	220cm	260cm	300cm	400cm	450cm	
10	Flexible part length in the distal tip	3 : 3cm (normal taper)								
11	Languages used for the indications	M : Multilanguage								

Super-Flex Type

R F * □ □ □ □ □ □ □ □ □
1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation			
	1-2	Product name	RADIFOCUS GUIDE WIRE M	
3	Destination	*: for export		
4	Core wire flexibility	G : Standard		
5	Tip configuration	V : J-angled (2mm)		
6-7	Outer diameter of guide wire	35: 0.035"		
8-9	Guide wire length	15	18	20
		150 cm	180 cm	200 cm
10	Flexible part length in the distal tip	1 : 1cm (short taper)		
11	Languages used for the indications	M : Multilanguage		

Shapeable Type (E Type)

R E * □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation					
1-2	Product name	RADIFOCUS GUIDE WIRE M				
3	Destination	*: for export				
4	Core wire flexibility	G : Standard				
5	Tip configuration	L : Straight K : Angled				
6-7	Outer diameter of guide wire	18	25	32	35	38
		0.018"	0.025"	0.032"	0.035"	0.038"
8-9	Guide wire length	12	15	18	22	26
		120cm	150cm	180cm	220cm	260cm
10	Flexible part length in the distal tip	3 : 3cm (normal taper)				
11	Languages used for the indications	M : Multi-language				

2) With radiopaque tip marker

R F * R
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Denotation			
1, 2, 4	Product name	RADIFOCUS GUIDE WIRE M		
3	Destination	*: for export		
5	Tip configuration (Angled)	A : 45° B : 70°		
6-7	Outer diameter of guide wire	10	14	16
		0.011"	0.014"	0.016"
8-9	Guide wire length	18 : 180cm		
10	Flexible part length in the distal tip	8 : 8cm (long long taper)		
11	Accessory supplied with the guide wire	T : Torque device		
12	Languages used for the indications	M : Multilanguage		

RADIFOCUS GUIDEWIRE M manufactured by TVC Product code system

Standard type

R F
1 2 3 4 5 6 7 8 9 10 11

Position	Meaning of indication							
1-2	Product type	RADIFOCUS GUIDE WIRE M						
3	Destination	+ / * for worldwide excluding Japan						
4	Core wire flexibility	G : Standard H : Half stiff P : Stiff						
5	Tip configuration	A : Angled S : Straight						
6-7	Outer diameter of guide wire	18				25		
		stiff-core type: 0.020" / 0.51 mm				0.025" / 0.64 mm		
		other core types: 0.018" / 0.46 mm						
8-9	Guide wire length	32		35		38		
		0.032" / 0.81 mm		0.035" / 0.89 mm		0.038" / 0.97 mm		
		05	08	12	15	18	22	
		50 cm	80 cm	120 cm	150 cm	180 cm	220 cm	
		26						
		260cm						
10	Flexible part length in distal tip	1 : 1cm (short taper) 3 : 3cm (normal taper) 5 : 5cm (long taper) 8 : 8cm (long long taper)						
11	Languages used for the indications	M : Multilanguage						

DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

RADIFOCUS Guide Wire M


Product : Catheter Guide Wire

declare that the above products of **Class III** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 (Registration No.: HD 60145252 0001), and Annex II, Section 4 (Registration No.: ID 60156558 0001) under the supervision of TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, June 3, 2021
(place and date of issue)


Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

RADIFOCUS GUIDEWIRE M Product code system

- 1) Without radiopaque tip marker
Standard type

R F * □ □ □ □ □ □ □ □ □ □
1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation						
1-2	Product name	RADIFOCUS GUIDE WIRE M					
3	Destination	* : for export					
4	Core wire flexibility	G : Standard H : Half stiff P : Stiff					
5	Tip configuration	A : Angled B : J-angled (3mm) C : J-angled (6mm) E : Double-angled N : J-angled (2mm) R : J-angled (1.5mm) S : Straight					
6-7	Outer diameter of guide wire	18				25	
		stiff-core type: 0.020" other core types: 0.018"					
		32		35		38	
		0.032"		0.035"		0.038"	
8-9	Guide wire length	05	07	08	12	15	18
		50 cm	70 cm	80 cm	120 cm	150 cm	180 cm
		22	26	30	35	40	45
		220 cm	260cm	300cm	350cm	400 cm	450 cm
10	Flexible part length in the distal tip	1 : 1cm (short taper) 3 : 3cm (normal taper) 5 : 5cm (long taper) 8 : 8cm (long long taper)					
11	Languages used for the indications	M : Multilanguage					

High Flex Type

 R F * □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation									
1-2	Product name	RADIFOCUS GUIDE WIRE M								
3	Destination	*: for export								
4	Core wire flexibility	G : Standard H : Half stiff								
5	Tip configuration	J : Straight F : Angled								
6-7	Outer diameter of guide wire	18	25	32	35	38				
		0.018"	0.025"	0.032"	0.035"	0.038"				
8-9	Guide wire length	12	15	18	22	26	30	40	45	
		120cm	150cm	180cm	220cm	260cm	300cm	400cm	450cm	
10	Flexible part length in the distal tip	3 : 3cm (normal taper)								
11	Languages used for the indications	M : Multilanguage								

Super-Flex Type

R F * □ □ □ □ □ □ □ □ □
1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation			
	1-2	Product name	RADIFOCUS GUIDE WIRE M	
3	Destination	*: for export		
4	Core wire flexibility	G : Standard		
5	Tip configuration	V : J-angled (2mm)		
6-7	Outer diameter of guide wire	35: 0.035"		
8-9	Guide wire length	15	18	20
		150 cm	180 cm	200 cm
10	Flexible part length in the distal tip	1 : 1cm (short taper)		
11	Languages used for the indications	M : Multilanguage		

Shapeable Type (E Type)

R E * □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11

Character number	Denotation					
1-2	Product name	RADIFOCUS GUIDE WIRE M				
3	Destination	*: for export				
4	Core wire flexibility	G : Standard				
5	Tip configuration	L : Straight K : Angled				
6-7	Outer diameter of guide wire	18	25	32	35	38
		0.018"	0.025"	0.032"	0.035"	0.038"
8-9	Guide wire length	12	15	18	22	26
		120cm	150cm	180cm	220cm	260cm
10	Flexible part length in the distal tip	3 : 3cm (normal taper)				
11	Languages used for the indications	M : Multi-language				

2) With radiopaque tip marker

R F * R
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Denotation			
1, 2, 4	Product name	RADIFOCUS GUIDE WIRE M		
3	Destination	*: for export		
5	Tip configuration (Angled)	A : 45° B : 70°		
6-7	Outer diameter of guide wire	10	14	16
		0.011"	0.014"	0.016"
8-9	Guide wire length	18 : 180cm		
10	Flexible part length in the distal tip	8 : 8cm (long long taper)		
11	Accessory supplied with the guide wire	T : Torque device		
12	Languages used for the indications	M : Multilanguage		

RADIFOCUS GUIDEWIRE M manufactured by TVC Product code system

Standard type

R F
1 2 3 4 5 6 7 8 9 10 11

Position	Meaning of indication							
1-2	Product type	RADIFOCUS GUIDE WIRE M						
3	Destination	+ / * for worldwide excluding Japan						
4	Core wire flexibility	G : Standard H : Half stiff P : Stiff						
5	Tip configuration	A : Angled S : Straight						
6-7	Outer diameter of guide wire	18				25		
		stiff-core type: 0.020" / 0.51 mm				0.025" / 0.64 mm		
		other core types: 0.018" / 0.46 mm						
8-9	Guide wire length	32		35		38		
		0.032" / 0.81 mm		0.035" / 0.89 mm		0.038" / 0.97 mm		
		05	08	12	15	18	22	
		50 cm	80 cm	120 cm	150 cm	180 cm	220 cm	
		26						
		260cm						
10	Flexible part length in distal tip	1 : 1cm (short taper) 3 : 3cm (normal taper) 5 : 5cm (long taper) 8 : 8cm (long long taper)						
11	Languages used for the indications	M : Multilanguage						

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 60134707 0001) and Annex II.4 (Registration No: ID 60156557 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, 12.10.2022

(place and date of issue)



K. Verhaert
Vice President Quality,
Regulatory and Vigilance
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	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		