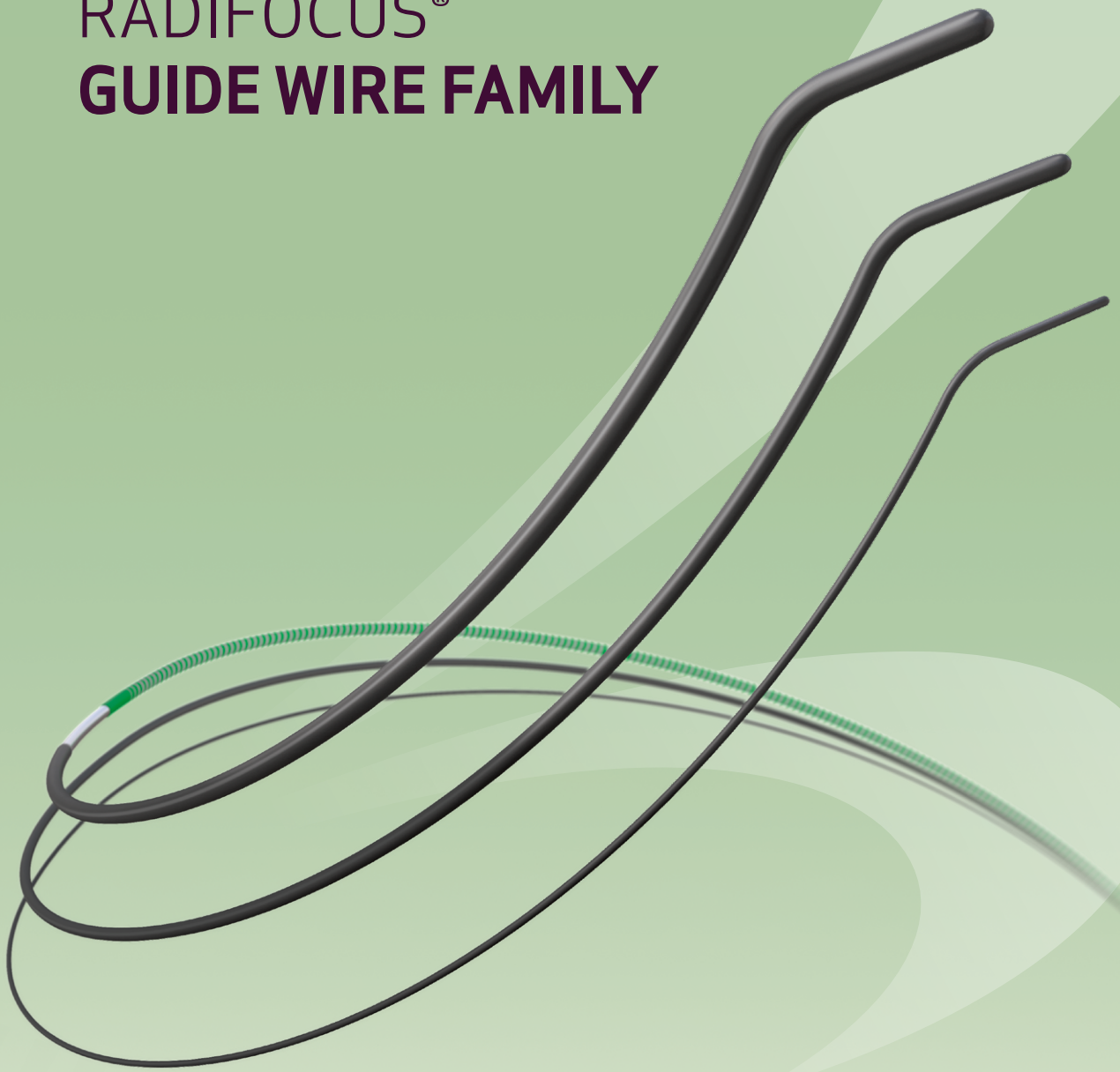
RADIFOCUS®
GUIDE WIRE FAMILY



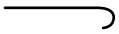
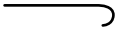
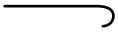
GLIDE WITH
CONFIDENCE

TERUMO
INTERVENTIONAL
SYSTEMS

RADIFOCUS®
Guide Wire M
J-Tip

- Nitinol guidewire covered with polyurethane containing tungsten and hydrophilic M Coat™
- Avoids the selection of side branches and minimizes the risk of procedural complications due to small J-shaped atraumatic tip[1]

ORDERING INFORMATION

Product code	Wire type	Outer diameter	Overall length	Flexible tip length	Tip shape
RF*GR35183M	Standard	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	1.5 mm J-tip 
RF*GR35263M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	
RF*HR35183M	Half stiff	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	
RF*HR35303M	Half stiff	0.035" (0.89 mm + 0.01 mm)*	300 cm	3 cm	
RF*HN35183M	Half stiff	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	2.0 mm J-Tip 
RF*GB35153M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	3.0 mm J-Tip 

* Nominal OD + upper tolerance, reflecting Maximal OD.
1. Barbeau G. et al. Radial Loop and Extreme Vessel Tortuosity in the Transradial Approach: Advantage of Hydrophilic-Coated Guidewires and Catheters. Catheterization and Cardiovascular Interventions 59:442-450 (2003).

RADIFOCUS®
Glidewire Advantage™

- M Coat™ hydrophilic coated polyurethane jacket at distal part provides trackability equal to Radifocus® Guide Wire M
- Extra stiff proximal shaft with spiral PTFE** coating provides good device support and very smooth sliding characteristics[1]
- Dedicated to all peripheral intervention levels, from sheath placement to ilio-femoro-popliteal and below-the-knee treatments[2]

ORDERING INFORMATION

Product code	Wire type	Outer diameter	Overall length	Distal hydrophilic coated length	Flexible tip length	Tip shape
RA*FA14181CM	Extra stiff	0.014" (0.36 mm + 0.00 mm)*	180 cm	25 cm	1 cm	45° Angled 
RA*FA14301CM	Extra stiff	0.014" (0.36 mm + 0.00 mm)*	300 cm	25 cm	1 cm	
RA*FA18181CM	Extra stiff	0.018" (0.46 mm + 0.00 mm)*	180 cm	25 cm	1 cm	
RA*FA18301CM	Extra stiff	0.018" (0.46 mm + 0.00 mm)*	300 cm	25 cm	1 cm	
RA*CA35185CM	Extra stiff	0.035" (0.89 mm + 0.00 mm)*	180 cm	25 cm	5 cm	
RA*CA35265CM	Extra stiff	0.035" (0.89 mm + 0.00 mm)*	260 cm	25 cm	5 cm	
RA*FS14301CM	Extra stiff	0.014" (0.36 mm + 0.00 mm)*	300 cm	25 cm	1 cm	Straight
RA*FS18301CM	Extra stiff	0.018" (0.46 mm + 0.00 mm)*	300 cm	25 cm	1 cm	
RA*CS35185CM	Extra stiff	0.035" (0.89 mm + 0.00 mm)*	180 cm	25 cm	5 cm	
RA*CS35265CM	Extra stiff	0.035" (0.89 mm + 0.00 mm)*	260 cm	25 cm	5 cm	

* Nominal OD + upper tolerance, reflecting Maximal OD.
** PTFE: Polytetrafluoroethylene
1. Compared to Radifocus® Guide Wire M.
2. Lorenzoni et al. Guidewires for lower extremity artery angioplasty: a review. EuroIntervention. 2015;11:799-807.

TERUMO INTERVENTIONAL SYSTEMS

IS725GB10201TII

RADIFOCUS®
Guide Wire GT

With Gold Coil

- Nitinol guidewire covered with polyurethane containing tungsten and hydrophilic M Coat™ as well as distal 2 cm gold coil
- Small diameters, long-tapered core and distal pre-shaped curves for superselective access of peripheral, coronary and cerebral vasculature

ORDERING INFORMATION

Product code	Outer diameter	Overall length	Flexible tip length	Tip shape
RG*GA1218SM	0.012" (0.30 mm + 0.02 mm)*	180 cm	25 cm	Angled 45° x 4 mm
RG*GE1218SM	0.012" (0.30 mm + 0.02 mm)*	180 cm	25 cm	Angled 90° x 4 mm
RG*GW1218SM	0.012" (0.30 mm + 0.02 mm)*	180 cm	25 cm	Double angled 90° + 150°
RG*GA1220SM	0.012" (0.30 mm + 0.02 mm)*	200 cm	25 cm	Angled 45° x 4 mm
RG*GE1220SM	0.012" (0.30 mm + 0.02 mm)*	200 cm	25 cm	Angled 90° x 4 mm
RG*GW1220SM	0.012" (0.30 mm + 0.02 mm)*	200 cm	25 cm	Double angled 90° + 150°
RG*GA1418SM	0.014" (0.36 mm + 0.02 mm)*	180 cm	25 cm	Angled 45° x 4 mm
RG*GE1418SM	0.014" (0.36 mm + 0.02 mm)*	180 cm	25 cm	Angled 90°x 4 mm
RG*GW1418SM	0.014" (0.36 mm + 0.02 mm)*	180 cm	25 cm	Double Angled 90°+ 150°
RG*GA1420SM	0.014" (0.36 mm + 0.02 mm)*	200 cm	25 cm	Angled 45°x 4 mm
RG*GE1420SM	0.014" (0.36 mm + 0.02 mm)*	200 cm	25 cm	Angled 90°x 4 mm
RG*GW1420SM	0.014" (0.36 mm + 0.02 mm)*	200 cm	25 cm	Double Angled 90° + 150°
RG*GA1618SM	0.016" (0.41 mm + 0.02 mm)*	180 cm	25 cm	Angled 45° x 4 mm
RG*GA1618FM	0.016" (0.41 mm + 0.02 mm)*	180 cm	35 cm	Angled 45° x 4 mm
RG*GE1618FM	0.016" (0.41 mm + 0.02 mm)*	180 cm	35 cm	Angled 90° x 4 mm
RG*GW1618FM	0.016" (0.41 mm + 0.02 mm)*	180 cm	35 cm	Double angled 90° + 150°
RG*GA1620FM	0.016" (0.41 mm + 0.02 mm)*	200 cm	35 cm	Angled 45° x 4 mm
RG*GE1620FM	0.016" (0.41 mm + 0.02 mm)*	200 cm	35 cm	Angled 90° x 4 mm
RG*GW1620FM	0.016" (0.41 mm + 0.02 mm)*	200 cm	35 cm	Double angled 90° + 150°

* Nominal OD + upper tolerance, reflecting Maximal OD.

1. Barbeau G. et al. Radial Loop and Extreme Vessel Tortuosity in the Transradial Approach: Advantage of Hydrophilic-Coated Guidewires and Catheters. Catheterization and Cardiovascular Interventions 59:442-450 (2003).

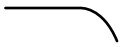
TERUMO INTERVENTIONAL SYSTEMS

IS725GB1020ITII

RADIFOCUS®
Guide Wire M
Stiff

- Nitinol guidewire covered with polyurethane containing tungsten and hydrophilic M Coat™
- Stiffer shaft[1] designed for tight, stenotic, tortuous and narrow vessels

ORDERING INFORMATION

Product code	Wire type	Outer diameter	Overall length	Flexible tip length	Tip shape
RF-PA18153M	Stiff	0.020" (0.51 mm + 0.01 mm)*	150 cm	3 cm	Angled 
RF-PA18263M	Stiff	0.020" (0.51 mm + 0.01 mm)*	260 cm	3 cm	
RF-PA25153M	Stiff	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	
RF-PA25183M	Stiff	0.025" (0.64 mm + 0.00 mm)*	180 cm	3 cm	
RF-PA25263M	Stiff	0.025" (0.64 mm + 0.00 mm)*	260 cm	3 cm	
RF-PA35083M	Stiff	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	
RF-PA35151M	Stiff	0.035" (0.89 mm + 0.01 mm)*	150 cm	1 cm	
RF*PA35153M	Stiff	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	
RF*PA35183M	Stiff	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	
RF-PA35263M	Stiff	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	
RF-PA35303M	Stiff	0.035" (0.89 mm + 0.01 mm)*	300 cm	3 cm	
RF-PA38153M	Stiff	0.038" (0.97 mm + 0.02 mm)*	150 cm	3 cm	
RF-PA38183M	Stiff	0.038" (0.97 mm + 0.02 mm)*	180 cm	3 cm	
RF-PA38263M	Stiff	0.038" (0.97 mm + 0.02 mm)*	260 cm	3 cm	
RF-PS25153M	Stiff	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	Straight
RF-PS35083M	Stiff	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	
RF-PS35153M	Stiff	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	
RF-PS35183M	Stiff	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	
RF-PS35263M	Stiff	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	
RF-PS38083M	Stiff	0.038" (0.97 mm + 0.02 mm)*	80 cm	3 cm	
RF-PS38153M	Stiff	0.038" (0.97 mm + 0.02 mm)*	150 cm	3 cm	
RF-PS38183M	Stiff	0.038" (0.97 mm + 0.02 mm)*	180 cm	3 cm	

* Nominal OD + upper tolerance, reflecting Maximal OD.

1. Compared to Radifocus® Guide Wire M Standard.

TERUMO INTERVENTIONAL SYSTEMS

IS725GB10201Ti

RADIFOCUS®
Guide Wire M
Standard

- Nitinol guidewire covered with polyurethane containing tungsten and hydrophilic M Coat™
- Designed to direct a catheter to the desired anatomical location during peripheral, coronary and cerebral interventions[1]

ORDERING INFORMATION

Product code	Wire type	Outer diameter	Overall length	Flexible tip length	Tip shape
RF-GA18053M	Standard	0.018" (0.46 mm + 0.02 mm)*	50 cm	3 cm	
RF-GA18153M	Standard	0.018" (0.46 mm + 0.02 mm)*	150 cm	3 cm	
RF-GA18183M	Standard	0.018" (0.46 mm + 0.02 mm)*	180 cm	3 cm	
RF-GA18223M	Standard	0.018" (0.46 mm + 0.02 mm)*	220 cm	3 cm	
RF-GA18263M	Standard	0.018" (0.46 mm + 0.02 mm)*	260 cm	3 cm	
RF-GA25053M	Standard	0.025" (0.64 mm + 0.00 mm)*	50 cm	3 cm	
RF-GA25123M	Standard	0.025" (0.64 mm + 0.00 mm)*	120 cm	3 cm	
RF-GA25153M	Standard	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	
RF-GA25183M	Standard	0.025" (0.64 mm + 0.00 mm)*	180 cm	3 cm	
RF-GA25263M	Standard	0.025" (0.64 mm + 0.00 mm)*	260 cm	3 cm	
RF-GA32123M	Standard	0.032" (0.81 mm + 0.00 mm)*	120 cm	3 cm	
RF-GA32153M	Standard	0.032" (0.81 mm + 0.00 mm)*	150 cm	3 cm	
RF-GA32183M	Standard	0.032" (0.81 mm + 0.00 mm)*	180 cm	3 cm	
RF-GA32263M	Standard	0.032" (0.81 mm + 0.00 mm)*	260 cm	3 cm	
RF-GA35053M	Standard	0.035" (0.89 mm + 0.01 mm)*	50 cm	3 cm	
RF-GA35083M	Standard	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	
RF-GA35123M	Standard	0.035" (0.89 mm + 0.01 mm)*	120 cm	3 cm	Angled
RF-GA35151M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	1 cm	
RF*GA35153M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	
RF-GA35155M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	5 cm	
RF-GA35158M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	8 cm	
RF-GA35181M	Standard	0.035" (0.89 mm + 0.01 mm)*	180 cm	1 cm	
RF*GA35183M	Standard	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	
RF-GA35223M	Standard	0.035" (0.89 mm + 0.01 mm)*	220 cm	3 cm	
RF-GA35261M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	1 cm	
RF*GA35263M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	
RF-GA35303M	Standard	0.035" (0.89 mm + 0.01 mm)*	300 cm	3 cm	
RF-GA38151M	Standard	0.038" (0.97 mm + 0.02 mm)*	150 cm	1 cm	
RF*GA38153M	Standard	0.038" (0.97 mm + 0.02 mm)*	150 cm	3 cm	
RF-GA38183M	Standard	0.038" (0.97 mm + 0.02 mm)*	180 cm	3 cm	
RF-GA38223M	Standard	0.038" (0.97 mm + 0.02 mm)*	220 cm	3 cm	
RF-GA38263M	Standard	0.038" (0.97 mm + 0.02 mm)*	260 cm	3 cm	

* Nominal OD + upper tolerance, reflecting Maximal OD.

1. Radifocus® Guide Wire M Standard IFU.

TERUMO INTERVENTIONAL SYSTEMS

IS725GB10201Ti

RADIFOCUS®
Guide Wire M
Standard

ORDERING INFORMATION

Product code	Wire type	Outer diameter	Overall length	Flexible tip length	Tip shape
RF-GS18153M	Standard	0.018" (0.46 mm + 0.02 mm)*	150 cm	3 cm	
RF-GS18183M	Standard	0.018" (0.46 mm + 0.02 mm)*	180 cm	3 cm	
RF-GS18263M	Standard	0.018" (0.46 mm + 0.02 mm)*	260 cm	3 cm	
RF-GS25123M	Standard	0.025" (0.64 mm + 0.00 mm)*	120 cm	3 cm	
RF-GS25153M	Standard	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	
RF-GS25183M	Standard	0.025" (0.64 mm + 0.00 mm)*	180 cm	3 cm	
RF-GS25263M	Standard	0.025" (0.64 mm + 0.00 mm)*	260 cm	3 cm	
RF-GS32123M	Standard	0.032" (0.81 mm + 0.00 mm)*	120 cm	3 cm	
RF-GS32153M	Standard	0.032" (0.81 mm + 0.00 mm)*	150 cm	3 cm	
RF-GS32183M	Standard	0.032" (0.81 mm + 0.00 mm)*	180 cm	3 cm	
RF-GS32263M	Standard	0.032" (0.81 mm + 0.00 mm)*	260 cm	3 cm	
RF-GS35123M	Standard	0.035" (0.89 mm + 0.01 mm)*	120 cm	3 cm	
RF-GS35151M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	1 cm	Straight ———
RF* GS35153M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	
RF-GS35155M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	5 cm	
RF-GS35158M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	8 cm	
RF-GS35181M	Standard	0.035" (0.89 mm + 0.01 mm)*	180 cm	1 cm	
RF-GS35183M	Standard	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	
RF-GS35223M	Standard	0.035" (0.89 mm + 0.01 mm)*	220 cm	3 cm	
RF-GS35261M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	1 cm	
RF-GS35263M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	
RF-GS38153M	Standard	0.038" (0.97 mm + 0.02 mm)*	150 cm	3 cm	
RF-GS38183M	Standard	0.038" (0.97 mm + 0.02 mm)*	180 cm	3 cm	
RF-GS38263M	Standard	0.038" (0.97 mm + 0.02 mm)*	260 cm	3 cm	

* Nominal OD + upper tolerance, reflecting Maximal OD.

TERUMO INTERVENTIONAL SYSTEMS

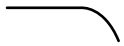
IS725GB1020ITII

RADIFOCUS® Guide Wire M

Non-Vascular

- Nitinol guidewire covered with polyurethane containing tungsten and hydrophilic M Coat™
- For the placement or exchange of devices during non-vascular procedures in endourology and cannulation or insertion of devices into the bile ducts and pancreatic duct[1]

ORDERING INFORMATION

Product code	Wire type	Outer diameter	Overall length	Flexible tip length	Tip shape
NV-GA18153M	Standard	0.018" (0.46 mm + 0.02 mm)*	150 cm	3 cm	Angled 
NV-GA25153M	Standard	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	
NV-GA32153M	Standard	0.032" (0.81 mm + 0.00 mm)*	150 cm	3 cm	
NV-GA32263M	Standard	0.032" (0.81 mm + 0.00 mm)*	260 cm	3 cm	
NV-GA32403M	Standard	0.032" (0.81 mm + 0.00 mm)*	400 cm	3 cm	
NV-GA35083M	Standard	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	
NV-GA35123M	Standard	0.035" (0.89 mm + 0.01 mm)*	120 cm	3 cm	
NV-GA35153M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	
NV-GA35263M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	
NV-GA35403M	Standard	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	
NV-GA35453M	Standard	0.035" (0.89 mm + 0.01 mm)*	450 cm	3 cm	
NV-PA18153M	Stiff	0.020" (0.51 mm + 0.01 mm)*	150 cm	3 cm	
NV-PA18453M	Stiff	0.020" (0.51 mm + 0.01 mm)*	450 cm	3 cm	
NV-PA25153M	Stiff	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	
NV-PA25453M	Stiff	0.025" (0.64 mm + 0.00 mm)*	450 cm	3 cm	
NV-PA35153M	Stiff	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	
NV-PA35263M	Stiff	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	
NV-PA35403M	Stiff	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	
NV-GS18153M	Standard	0.018" (0.46 mm + 0.02 mm)*	150 cm	3 cm	Straight
NV-GS25153M	Standard	0.025" (0.64 mm + 0.00 mm)*	150 cm	3 cm	
NV-GS32153M	Standard	0.032" (0.81 mm + 0.00 mm)*	150 cm	3 cm	
NV-GS32263M	Standard	0.032" (0.81 mm + 0.00 mm)*	260 cm	3 cm	
NV-GS32403M	Standard	0.032" (0.81 mm + 0.00 mm)*	400 cm	3 cm	
NV-GS35123M	Standard	0.035" (0.89 mm + 0.01 mm)*	120 cm	3 cm	
NV-GS35153M	Standard	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	
NV-GS35183M	Standard	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	
NV-GS35263M	Standard	0.035" (0.89 mm + 0.01 mm)*	260 cm	3 cm	
NV-GS35403M	Standard	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	
NV-GS35453M	Standard	0.035" (0.89 mm + 0.01 mm)*	450 cm	3 cm	
NV-GS38153M	Standard	0.038" (0.97 mm + 0.02 mm)*	150 cm	3 cm	
NV-PS18453M	Stiff	0.020" (0.51 mm + 0.01 mm)*	450 cm	3 cm	
NV-PS25453M	Stiff	0.025" (0.64 mm + 0.00 mm)*	450 cm	3 cm	
NV-PS35083M	Stiff	0.035" (0.89 mm + 0.01 mm)*	80 cm	3 cm	
NV-PS35153M	Stiff	0.035" (0.89 mm + 0.01 mm)*	150 cm	3 cm	
NV-PS35183M	Stiff	0.035" (0.89 mm + 0.01 mm)*	180 cm	3 cm	
NV-PS35403M	Stiff	0.035" (0.89 mm + 0.01 mm)*	400 cm	3 cm	
NV-PS38153M	Stiff	0.038" (0.97 mm + 0.02 mm)*	150 cm	3 cm	
NV-PS38183M	Stiff	0.038" (0.97 mm + 0.02 mm)*	180 cm	3 cm	

* Nominal OD + upper tolerance, reflecting Maximal OD.

1. Radifocus® Guide Wire M Non-Vascular IFU.

IS725GB10201Ti

TERUMO INTERVENTIONAL SYSTEMS

EU Certificate

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

TÜVRheinland®

Registration No.:	HZ 1485480-1
Manufacturer:	**Terumo Corporation** 44-1, 2-chome, Hatagaya Shibuya-ku, Tokyo 151-0072 Japan
EUDAMED Single Registration No.:	JP-MF-000017478
Products:	Products of class Is: B019004 - BLOOD COMPONENTS SAMPLING BAGS AND KITS C900103 - PERCUTANEOUS ARTERIAL ACCESS HAEMOSTASIS SYSTEMS The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions Products of class IIa: A010101 - HYPODERMIC NEEDLES A010601 - CARPULE NEEDLES A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE C010101 - PERIPHERAL I.V. CATHETERS C030101 - EXTRACORPOREAL CIRCULATION KITS Z121799 - BLOOD TRANSFUSION INSTRUMENTS - OTHER A010102 - BUTTERFLY NEEDLES A019099 - NEEDLES FOR OTHER PROCEDURES – OTHER G0399- DIGESTIVE ENDOSCOPY DEVICES – OTHER C040201 - PERIPHERAL VASCULAR DIAGNOSTIC GUIDEWIRES C040202 - PERIPHERAL VASCULAR THERAPEUTIC GUIDEWIRES

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.:	150276493-307
Effective date:	2023-08-30
Expiry date:	2025-05-28
Issue date:	2023-08-30

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜVRheinland®

Registration No.: HZ 1485480-1

Manufacturer:

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

Products of class IIb:
B010202 - BLOOD TRANSFER BAGS AND KITS
PLATELETS CONCENTRATE TRANSFER BAGS AND KITS
Intended Purpose: TERUFLEX BP-KIT with IMUGARD III-SPL is intended for pooling up to six buffy-coats, for in process filtration and preservation of leukocyte removed platelet concentrate.
B010202 - BLOOD TRANSFER BAGS AND KITS
PLATELETS CONCENTRATE TRANSFER BAGS AND KITS
Intended Purpose: TERUFLEX BP-KIT is intended for pooling up to six buffy-coats, for in process separation and preservation of platelet concentrates.
B010201 - BLOOD TRANSFER BAGS AND KITS
WHOLE BLOOD, RED BLOOD CELLS OR PLASMA TRANSFER BAGS AND KITS
Intended Purpose: TERUFLEX TRANSFER BAG is intended for separating and storing each blood component.

Products of class III:
C010401 - ANGIOGRAPHY AND HAEMODYNAMIC DEVICES
CARDIAC ANGIOGRAPHY DEVICES
Intended Purpose: Use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guide wire or a catheter into the target site.

Authorised representative(s):

Terumo Europe N.V.
Interleuvenlaan 40
3001 Leuven Belgium

Terumo BCT Europe N.V.
Ikaroslaan 41
1930 Zaventem Belgium

Report No.: 150276493-307

Effective date: 2023-08-30

Expiry date: 2025-05-28

Issue date: 2023-08-30

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜVRheinland®

Registration No.: HZ 1485480-1

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

Certificate history		
Revision:	Description:	Issue date:
0	Initial	2020-05-29
1	Added product (C030101)	2021-05-07
2	Added product (Z121799) and Authorised representative	2022-03-29
3	Added product (A010102)	2022-04-28
4	Added product (B010202)	2022-07-25
5	Added product (A019099)	2022-08-01
6	Added product (B019004)	2022-08-24
7	Minor amendment of Intended Purpose (B010202) & Added product (C010401)	2022-12-21
8	Added product (B010202) of different Intended Purpose	2023-02-20
9	Added product (C900103)	2023-03-29
10	Added Product (G0399)	2023-07-28
11	Added Product (B010201)	2023-08-15
12	Added product (C040201, C040202)	2023-08-30

Report No.: 150276493-307

Effective date: 2023-08-30

Expiry date: 2025-05-28

Issue date: 2023-08-30

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

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

Scope: Design and Development, Manufacture, Distribution and Service of
- Angiographic Catheter and Accessories
- Anti-adhesion System
- Balloon Dilatation Catheter
- Blood Collection/Transfusion Device and Accessories
- Blood Glucose Monitoring system
- Cartridge Injection System
- Catheter Introducer and Accessories
- Electronic Sphygmomanometer
- Electronic Thermometer
- Embolization Prosthesis and Accessories
- Extracorporeal Circulation Device and Accessories
- Falloposcopic Tuboplasty Device and Accessories
- Guide Wire and Accessories
- Guiding/Micro Catheter and Accessories
- Infusion Pump
- Infusion Set and Accessories
- Intravascular Imaging Catheter and Accessories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150276465-301
Effective date: 2023-08-30
Expiry date: 2026-08-29
Issue date: 2023-07-20

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

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

- Intravascular Imaging System and Accessories
- Intravenous Catheter
- Left-Ventricular Assist System
- Needle
- Open-heart surgery devices and Accessories
- Oral Care Device and Accessories
- Peritoneal Dialysis Device and Accessories
- Pneumatically-powered Massager
- Prefillable Syringe
- Pulse Oximeter
- Radial Artery Hemostasis Device and Accessories
- Stent System
- Syringe
- Syringe Infusion Pump
- Syringe with Needle
- Thrombus Removal Device
- Tube Catheter and Accessories
- Urine test strip
- Vascular Closure Device
- Vascular Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

Report No.: 150276465-301
Effective date: 2023-08-30
Expiry date: 2026-08-29
Issue date: 2023-07-20

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Terumo Corporation 44-1, 2-chome, Hatagaya Shibuya-ku, Tokyo 151-0072 Japan	Aspects related to Design and Development, Manufacture, Distribution and Service.
/02	c/o Terumo Corporation - Tokyo office 3-20-2, Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Aspects related to Design and Development and activities related to corporate management processes.
/03	c/o Terumo Corporation, Shonan Center 1500, Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Aspects related to Distribution and activities related to customer communication processes.

Report No.: 150276465-301
Effective date: 2023-08-30
Expiry date: 2026-08-29
Issue date: 2023-07-20

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

+

Terumo Europe N.V.

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Interleuvenlaan 40
3001 Leuven, Belgium
Tel.: +32 16 38 12 11
Fax: +32 16 40 02 49

www.terumo-europe.com

PCN 220916-01

Leuven, 30 October 2023

To whom it may concern,

Subject: ***Overview of MDR changes – Radifocus Glidewire Advantage – manufactured by Terumo Corporation.***

Dear,

With this letter we would like to notify you that **Radifocus Glidewire Advantage** manufactured by Terumo Corporation (TC) obtained the MDR certification. This letter is to inform you of all the major updates that will be implemented with the start of the production of the MDR product.

This change **will not have an impact** on the design or quality of the product, neither on the product codes.

The codes below (Track codes) will transition to MDR in a later stage. Therefore, we would like to request your support to notify the new MDR documents AND maintain the MDD notification in your reference country(ies) in order to be able to continue to import those codes. All MDD documents (DoC and CE Certificates) remain valid and will be used to place on the market the Track codes.

RA*GB18181CM	RA*GB18301CM	RA*GB14181CM	RA*GB14301CM

The table below gives an overview of the major changes performed on the device's documentation, of which one or more may have been used to notify the device in your country.

Change	**Description**	**Possible registration documents impacted**	**Supportive material**
MDR certificates	First issue	EU Quality Management System Certificate	Attachment 1 – MDR certificate
MDR Declaration of Conformity	First issue	DoC (DoC No. DOC-DC-0088851 rev.00)	Attachment 2 – Declaration of Conformity
MDR labelling	Updated to reflect the MDR requirements		Attachment 3 - New MDR artworks
IFU changes	Updated to reflect the MDR requirements		Attachment 4 - New MDR IFU
Discontinuation of Codes	RA*FS18181CM and RA*FS14181CM will not be produced under MDR	List of codes	N/A

With this letter we are providing the required documents for updating the local product notification file.
Thank you in advance for informing us when the MDR changes have been recorded at your end.

Should you have additional questions, please do not hesitate to contact us.

Best regards,

Valeria Piattelli
Regulatory Affairs Officer
Terumo Europe N.V.

Rev. 00
DoC No. DOC-DC-0088851
Reference to. DC-0088851

EU DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
with Single Registration Number: JP-MF-000017478

being the manufacturer of:

RADIFOCUS Glidewire Advantage

[PERIPHERAL VASCULAR DIAGNOSTIC GUIDEWIRES]/
[PERIPHERAL VASCULAR THERAPEUTIC GUIDEWIRES]

Intended purpose: The RADIFOCUS Glidewire Advantage is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures, except for the heart or central circulatory system.

Basic UDI-DI: 498735026ADVQZ

Related product codes: See Appendix A (full list of active codes)

declare that the above product of **Class IIa** is in conformity with the 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 Chapter I & III (EU quality management system certificate number HZ 1485480-1), 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.

There is no reference to Common Specifications that have been used to within the conformity assessment for Regulation (EU) 2017/745.

Authorised Representative: TERUMO EUROPE N.V.
Authorised Address: Interleuvenlaan 40, 3001 Leuven, Belgium
with Single Registration Number: BE-AR-000001433

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

Tokyo, 2023-10-16
(place and date of issue)

DocuSigned by:
Signer Name: Toshio Nakashima
Signing Reason: I approve this document
Signing Time: 2023-10-16 | 4:17:26 午後 JST
7CB53CAEA6904D2895AFA45B61783210

Toshio Nakashima
General Manager
Quality Assurance Department
For and on behalf of
TERUMO CORPORATION

Appendix A – Related product codes

Product code	UDI-DI
RA*CA35185CM	04987350705822
RA*CA35265CM	04987350705846
RA*CS35185CM	04987350721662
RA*CS35265CM	04987350721686
RA*FA18181CM	04987350486356
RA*FA18301CM	04987350486370
RA*FS18301CM	04987350725240
RA*FA14181CM	04987350486318
RA*FA14301CM	04987350486332
RA*FS14301CM	04987350725226

DocuSign

完了証明書

エンベロープID: 40742358114942B783AF611E62C0B2EE
ステータス: 完了
件名: DocuSignで送信: Class IIa_RADIFOCUS Glidewire Advantage_Rev.00
ソースエンベロープ:
文書ページ数: 2
署名: 1
エンベロープ差出人:
証明書ページ数: 5
イニシャル: 0
Saya Shiraishi
自動ナビゲーション: 有効
3-20-2 Nishi-Shinjuku
エンベロープIDスタンプ: 有効
Tokyo Opera City Tower 49F
タイムゾーン: (UTC+09:00)大阪、札幌、東京
Shinjuku-ku, Tokyo 163-1450
Saya_Shiraishi@terumo.co.jp
IPアドレス: 60.118.124.139

レコードの追跡

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場所: DocuSign
2023-10-16 | 16:18
ML-TC-QAD_DocuSign@terumo.co.jp

署名者イベント	署名	タイムスタンプ
Toshio Nakashima Toshio_Nakashima@terumo.co.jp セキュリティレベル: メール, アカウント認証(必須)	 署名の選択: 署名画像のアップロード 署名ID: 7CB53CAE-A690-4D28-95AF-A45B61783210 使用IPアドレス: 220.148.154.81 DocuSignパスワードによる署名認証 署名の理由付き(各タブ上): I approve this document	送信: 2023-10-16 | 13:50 表示: 2023-10-16 | 16:15 署名: 2023-10-16 | 16:17

電子記録および電子署名の開示条件:
同意: 2023-10-16 | 16:17
ID: 6a3c4da9-6405-49bd-a3f4-028e73268529

同席署名者イベント	署名	タイムスタンプ

編集者配信イベント	ステータス	タイムスタンプ

代理人配信イベント	ステータス	タイムスタンプ

仲介者配信イベント	ステータス	タイムスタンプ

証明書付き配信イベント	ステータス	タイムスタンプ

カーボンコピーイベント	ステータス	タイムスタンプ
Saya Shiraishi Saya_Shiraishi@terumo.co.jp TERUMO CORPORATION セキュリティレベル: メール, アカウント認証(必須)	コピー済み	送信: 2023-10-16 | 16:18 表示: 2023-10-16 | 16:18 署名: 2023-10-16 | 16:18

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馬場 允史 Masafumi_Baba@terumo.co.jp セキュリティレベル: メール, アカウント認証(必須) 電子記録および電子署名の開示条件: DocuSignで設定されていません	コピー済み	送信: 2023-10-16 | 16:17
佐藤 圭佑 Keisuke_Sato@terumo.co.jp TERUMO CORPORATION セキュリティレベル: メール, アカウント認証(必須) 電子記録および電子署名の開示条件: DocuSignで設定されていません	コピー済み	送信: 2023-10-16 | 16:17

立会人イベント	署名	タイムスタンプ

公証人イベント	署名	タイムスタンプ

エンベロープ概要イベント	ステータス	タイムスタンプ
エンベロープの送信	ハッシュ/暗号化済み	2023-10-16 | 13:50
証明書付き配信	セキュリティ確認済み	2023-10-16 | 16:15
署名の完了	セキュリティ確認済み	2023-10-16 | 16:17
完了	セキュリティ確認済み	2023-10-16 | 16:17

支払いイベント	ステータス	タイムスタンプ

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Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Terumo Corporation:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To notify Terumo Corporation of change in your email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at HOUMUSHITSU@terumo.co.jp and in the body of such request you must state: your previous email address, your new email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Terumo Corporation

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to HOUMUSHITSU@terumo.co.jp and in

the body of such request you must state your email address, full name, mailing address, and telephone number.

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To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to HOUMUSHITSU@terumo.co.jp and in the body of such request you must state your email, full name, mailing address, and telephone number.

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The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

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- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Terumo Corporation as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Terumo Corporation during the course of your relationship with Terumo Corporation.

Rev. 00
DoC No. DOC-DC-0088851
Reference to. DC-0088851

EU DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
with Single Registration Number: JP-MF-000017478

being the manufacturer of:

RADIFOCUS Glidewire Advantage

[PERIPHERAL VASCULAR DIAGNOSTIC GUIDEWIRES]/
[PERIPHERAL VASCULAR THERAPEUTIC GUIDEWIRES]

Intended purpose: The RADIFOCUS Glidewire Advantage is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures, except for the heart or central circulatory system.

Basic UDI-DI: 498735026ADVQZ

Related product codes: See Appendix A (full list of active codes)

declare that the above product of **Class IIa** is in conformity with the 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 Chapter I & III (EU quality management system certificate number HZ 1485480-1), 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.

There is no reference to Common Specifications that have been used to within the conformity assessment for Regulation (EU) 2017/745.

Authorised Representative: TERUMO EUROPE N.V.
Authorised Address: Interleuvenlaan 40, 3001 Leuven, Belgium
with Single Registration Number: BE-AR-000001433

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

Tokyo, 2023-10-16
(place and date of issue)

DocuSigned by:
Signer Name: Toshio Nakashima
Signing Reason: I approve this document
Signing Time: 2023-10-16 | 4:17:26 午後 JST
7CB53CAEA6904D2895AFA45B61783210

Toshio Nakashima
General Manager
Quality Assurance Department
For and on behalf of
TERUMO CORPORATION

Appendix A – Related product codes

Product code	UDI-DI
RA*CA35185CM	04987350705822
RA*CA35265CM	04987350705846
RA*CS35185CM	04987350721662
RA*CS35265CM	04987350721686
RA*FA18181CM	04987350486356
RA*FA18301CM	04987350486370
RA*FS18301CM	04987350725240
RA*FA14181CM	04987350486318
RA*FA14301CM	04987350486332
RA*FS14301CM	04987350725226

DocuSign

完了証明書

エンベロープID: 40742358114942B783AF611E62C0B2EE
ステータス: 完了
件名: DocuSignで送信: Class IIa_RADIFOCUS Glidewire Advantage_Rev.00
ソースエンベロープ:
文書ページ数: 2
署名: 1
エンベロープ差出人:
証明書ページ数: 5
イニシャル: 0
Saya Shiraishi
自動ナビゲーション: 有効
3-20-2 Nishi-Shinjuku
エンベロープIDスタンプ: 有効
Tokyo Opera City Tower 49F
タイムゾーン: (UTC+09:00)大阪、札幌、東京
Shinjuku-ku, Tokyo 163-1450
Saya_Shiraishi@terumo.co.jp
IPアドレス: 60.118.124.139

レコードの追跡

ステータス: オリジナル
保持者: Saya Shiraishi
場所: DocuSign
2023-10-16 | 11:23
Saya_Shiraishi@terumo.co.jp
ステータス: オリジナル
保持者: 品質保証部 文書管理用アカウント
場所: DocuSign
2023-10-16 | 16:18
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