

Glidewire Advantage[®]

Peripheral guidewire



Radifocus[®] Glidewire Advantage[™] are hybrid extra-stiff Nitinol hydrophilic guidewires covered with polyurethane containing tungsten and an hydrophilic polymer coating (M Coat) for peripheral procedures.

Indicated for use for standard angiography procedures in peripheral territories, catheterization, embolization, peripheral angioplasty and stenting (with or without exchange wire) in narrow and tortuous vessels.

Product Characteristics

- **Super elastic Nitinol core:** excellent shape memory, greater flexibility, increased control in difficult cases. Prevents kinking for an easier and faster catheter placement.
- **Dual hybrid structure which allows 2 jobs with one wire:** cross the lesion and support the interventional device delivery. No wire exchange, lower complications risk, shorter procedure and fluoroscopy time.
- **Extra stiff proximal core shaft with spiral PTFE polytetrafluoroethylene coating:** provide sufficient device support and very smooth sliding characteristics even in complex anatomies.
- **25 cm distal part:** standard Terumo Radifocus[®] hydrophilic guidewire, smooth surface minimizing blood adhesion. Allows soft atraumatic navigation and delivery to the lesion. Exclusive Terumo M Coat polymer: smooth distal navigation (no friction) through catheter and vessels (time savings to user).
- **Proximal and distal shafts connected seamlessly with unique DuoCore[™] fusing technology** for a smooth transition and navigation through vessels.
- **Rounded end:** decreased likelihood of vessel trauma, smoother wire insertion.
- **High visibility of the tip** due to the distal gold marker (for 0.014" and 0.018").

General Specifications

Core material	Nitinol
Proximal part	155 cm / 235 cm / 275 cm spiral PTFE coated shaft
Distal radiopaque jacket	25 cm Polyurethane layer containing tungsten
Distal hydrophilic coating	"M" polymer (M Coat [®])
Guidewire diameter	0.014" (0.36 mm) / 0.018" (0.46 mm) / 0.035" (0.89 mm)
Guidewire lengths	180 cm / 260 cm / 300 cm
Distal flexible length	Tapered 10 mm or 50 mm
Distal hydrophilic coated plastic part length	25 cm

Item Specifications

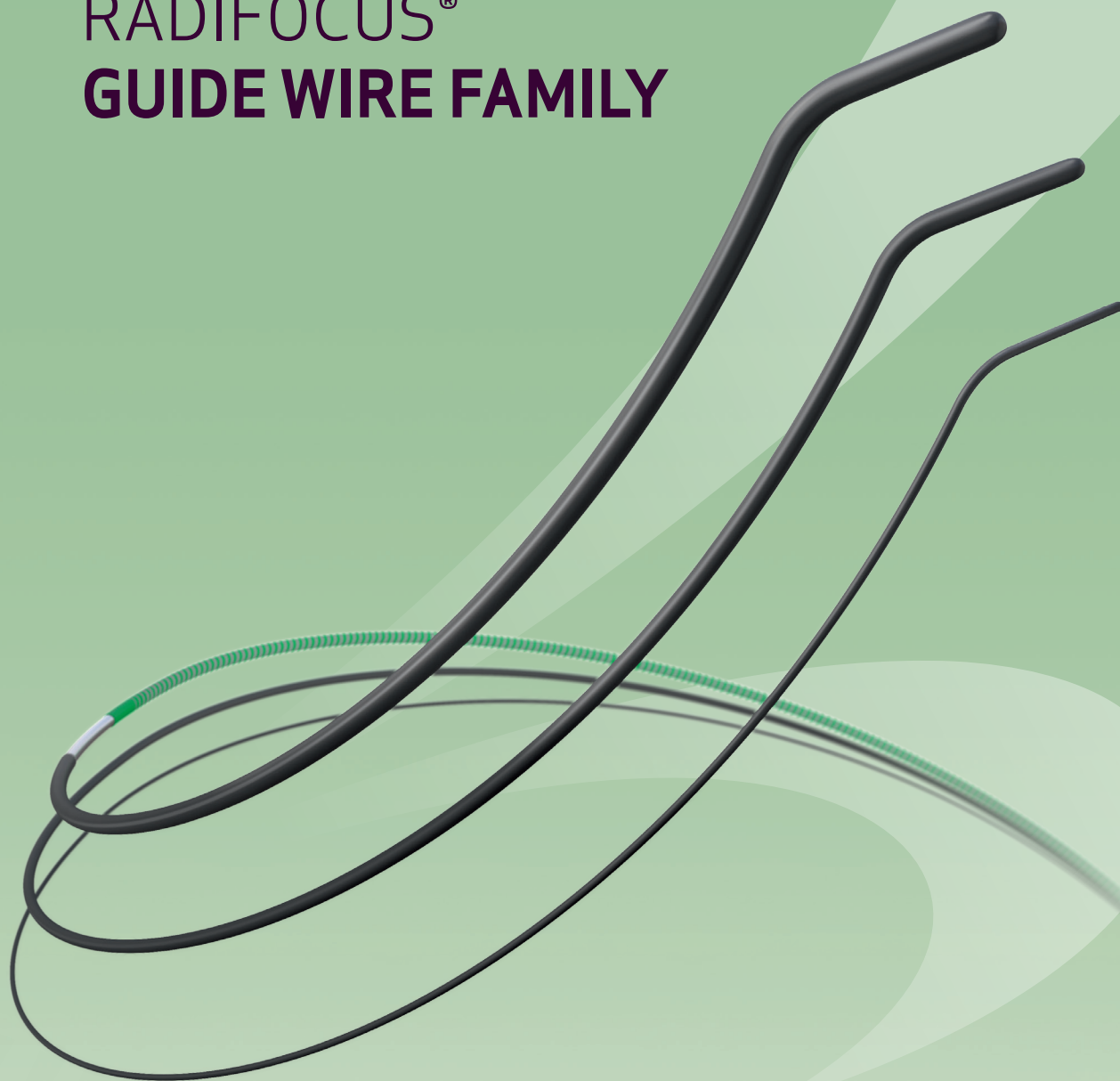
Product code	Shaft	Tip coil marker	Wire diameter	Overall length	Proximal spiral PTFE coating length	Distal hydrophilic coated length	Flexible tip length (taper)	Tip figure
RA*FA14181CM	Extra stiff	Yes	0.014" / 0.36 mm	180 cm	155 cm	25 cm	1 cm	Angled
RA*FA14301CM	Extra stiff	Yes	0.014" / 0.36 mm	300 cm	275 cm	25 cm	1 cm	Angled
RA*FS14301CM	Extra stiff	Yes	0.014" / 0.36 mm	300 cm	275 cm	25 cm	1 cm	Straight
RA*FA18181CM	Extra stiff	Yes	0.018" / 0.46 mm	180 cm	155 cm	25 cm	1 cm	Angled
RA*FA18301CM	Extra stiff	Yes	0.018" / 0.46 mm	300 cm	275 cm	25 cm	1 cm	Angled
RA*FS18301CM	Extra stiff	Yes	0.018" / 0.46 mm	300 cm	275 cm	25 cm	1 cm	Straight
RA*CA35185CM	Extra stiff	No	0.035" / 0.89 mm	180 cm	155 cm	25 cm	5 cm	Angled
RA*CA35265CM	Extra stiff	No	0.035" / 0.89 mm	260 cm	235 cm	25 cm	5 cm	Angled
RA*CS35185CM	Extra stiff	No	0.035" / 0.89 mm	180 cm	155 cm	25 cm	5 cm	Straight
RA*CS35265CM	Extra stiff	No	0.035" / 0.89 mm	260 cm	235 cm	25 cm	5 cm	Straight

Please quote above item reference code when placing an order

119190937/1919138



RADIFOCUS® GUIDE WIRE FAMILY



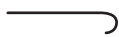


GLIDE WITH
CONFIDENCE

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 tip¹

ORDERING INFORMATION



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

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 characteristics¹
- Dedicated to all peripheral intervention levels, from sheath placement to ilio-femoro-popliteal and below-the-knee treatments²

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	180 cm	25 cm	1 cm	Angled 
RA*FA14301CM	Extra stiff	0.014" / 0.36 mm	300 cm	25 cm	1 cm	
RA*FA18181CM	Extra stiff	0.018" / 0.46 mm	180 cm	25 cm	1 cm	
RA*FA18301CM	Extra stiff	0.018" / 0.46 mm	300 cm	25 cm	1 cm	
RA*CA35185CM	Extra stiff	0.035" / 0.89 mm	180 cm	25 cm	5 cm	
RA*CA35265CM	Extra stiff	0.035" / 0.89 mm	260 cm	25 cm	5 cm	Straight 
RA*FS14301CM	Extra stiff	0.014" / 0.36 mm	300 cm	25 cm	1 cm	
RA*FS18301CM	Extra stiff	0.018" / 0.46 mm	300 cm	25 cm	1 cm	
RA*CS35185CM	Extra stiff	0.035" / 0.89 mm	180 cm	25 cm	5 cm	
RA*CS35265CM	Extra stiff	0.035" / 0.89 mm	260 cm	25 cm	5 cm	

*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.

RADIFOCUS® Guide Wire M

Shapeable

- Nitinol guidewire covered with polyurethane containing tungsten and hydrophilic M Coat™
- Shapeable tip to access acute-angled vessels during peripheral, cerebral and coronary interventions

ORDERING INFORMATION


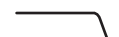
Product code	Wire type	Outer diameter	Overall length	Flexible tip length	Tip shape
RE*GK35153M	Standard	0.035" / 0.89 mm	150 cm	3 cm	45° Angled 
RE*GK35183M	Standard	0.035" / 0.89 mm	180 cm	3 cm	
RE*GL35153M	Standard	0.035" / 0.89 mm	150 cm	3 cm	Straight 
RE*GL35183M	Standard	0.035" / 0.89 mm	180 cm	3 cm	

RADIFOCUS® Guide Wire M

Radiopaque Tip Marker

- Nitinol guidewire covered with polyurethane containing tungsten and hydrophilic M Coat™ as well as distal gold tip marker
- Designed for improved visibility¹ when navigating microvessels in peripheral, cerebral and coronary vasculature

ORDERING INFORMATION

Product code	Outer diameter	Overall length	Flexible tip length	Tip shape
RF*RA10188TM	0.011" / 0.28 mm	180 cm	8 cm	45° Angled 
RF*RA16188TM	0.016" / 0.41 mm	180 cm	8 cm	
RF*RA18188TM	0.018" / 0.46 mm	180 cm	8 cm	
RF*RB10188TM	0.011" / 0.28 mm	180 cm	8 cm	70° Angled 
RF*RB16188TM	0.016" / 0.41 mm	180 cm	8 cm	
RF*RB18188TM	0.018" / 0.46 mm	180 cm	8 cm	

1. Compared to Radifocus® Guide Wire M Standard.

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

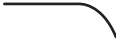

Product code	Outer diameter	Overall length	Flexible tip length	Tip shape
RG*GA1218SM	0.012" / 0.30 mm	180 cm	25 cm	Angled 45° x 4 mm
RG*GE1218SM	0.012" / 0.30 mm	180 cm	25 cm	Angled 90° x 4 mm
RG*GJ1218SM	0.012" / 0.30 mm	180 cm	25 cm	Angled 1.5 mm J curve
RG*GW1218M	0.012" / 0.30 mm	180 cm	25 cm	Double angled 90° + 150°
RG*GA1220SM	0.012" / 0.30 mm	200 cm	25 cm	Angled 45° x 4 mm
RG*GE1220SM	0.012" / 0.30 mm	200 cm	25 cm	Angled 90° x 4 mm
RG*GJ1220SM	0.012" / 0.30 mm	200 cm	25 cm	Angled 1.5 mm J curve
RG*GW1220M	0.012" / 0.30 mm	200 cm	25 cm	Double angled 90° + 150°
RG*GA1418SM	0.014" / 0.036 mm	180 cm	25 cm	Angled 45° x 4 mm
RG*GE1418SM	0.014" / 0.036 mm	180 cm	25 cm	Angled 90° x 4 mm
RG*GW1418M	0.014" / 0.036 mm	180 cm	25 cm	Double Angled 90° + 150°
RG*GA1420SM	0.014" / 0.036 mm	200 cm	25 cm	Angled 45° x 4 mm
RG*GE1420SM	0.014" / 0.036 mm	200 cm	25 cm	Angled 90° x 4 mm
RG*GW1420M	0.014" / 0.036 mm	200 cm	25 cm	Double Angled 90° + 150°
RG*GA1618SM	0.016" / 0.41 mm	180 cm	25 cm	Angled 45° x 4 mm
RG*GA1618FM	0.016" / 0.41 mm	180 cm	35 cm	Angled 45° x 4 mm
RG*GE1618FM	0.016" / 0.41 mm	180 cm	35 cm	Angled 90° x 4 mm
RG*GW1618M	0.016" / 0.41 mm	180 cm	35 cm	Double angled 90° + 150°
RG*GV1618SM	0.016" / 0.41 mm	180 cm	25 cm	Double Angled 90° + 90°
RG*GA1620FM	0.016" / 0.41 mm	200 cm	35 cm	Angled 45° x 4 mm
RG*GE1620FM	0.016" / 0.41 mm	200 cm	35 cm	Angled 90° x 4 mm
RG*GW1620M	0.016" / 0.41 mm	200 cm	35 cm	Double angled 90° + 150°
RG*GJ1620FM	0.016" / 0.41 mm	200 cm	35 cm	Angled 1.5 mm J curve

RADIFOCUS® Guide Wire M

Stiff

- Nitinol guidewire covered with polyurethane containing tungsten and hydrophilic M Coat™
- Stiffer shaft¹ 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	150 cm	3 cm	Angled 
RF-PA18263M	Stiff	0.020"/0.51 mm	260 cm	3 cm	
RF-PA25153M	Stiff	0.025"/0.64 mm	150 cm	3 cm	
RF-PA25183M	Stiff	0.025"/0.64 mm	180 cm	3 cm	
RF-PA25263M	Stiff	0.025"/0.64 mm	260 cm	3 cm	
RF-PA35083M	Stiff	0.035"/0.89 mm	80 cm	3 cm	
RF-PA35151M	Stiff	0.035"/0.89 mm	150 cm	1 cm	
RF*PA35153M	Stiff	0.035"/0.89 mm	150 cm	3 cm	
RF*PA35183M	Stiff	0.035"/0.89 mm	180 cm	3 cm	
RF*PA35188M	Stiff	0.035"/0.89 mm	180 cm	8 cm	
RF-PA35263M	Stiff	0.035"/0.89 mm	260 cm	3 cm	
RF-PA35303M	Stiff	0.035"/0.89 mm	300 cm	3 cm	
RF-PA38153M	Stiff	0.038"/0.97 mm	150 cm	3 cm	
RF-PA38183M	Stiff	0.038"/0.97 mm	180 cm	3 cm	
RF-PA38263M	Stiff	0.038"/0.97 mm	260 cm	3 cm	
RF-PS25153M	Stiff	0.025"/0.64 mm	150 cm	3 cm	Straight 
RF-PS25263M	Stiff	0.025"/0.64 mm	260 cm	3 cm	
RF-PS35083M	Stiff	0.035"/0.89 mm	80 cm	3 cm	
RF-PS35153M	Stiff	0.035"/0.89 mm	150 cm	3 cm	
RF-PS35183M	Stiff	0.035"/0.89 mm	180 cm	3 cm	
RF-PS35263M	Stiff	0.035"/0.89 mm	260 cm	3 cm	
RF-PS35453M	Stiff	0.035"/0.89 mm	450 cm	3 cm	
RF-PS38083M	Stiff	0.038"/0.97 mm	80 cm	3 cm	
RF-PS38153M	Stiff	0.038"/0.97 mm	150 cm	3 cm	
RF-PS38183M	Stiff	0.038"/0.97 mm	180 cm	3 cm	

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).



1. Compared to Radifocus® Guide Wire M Standard.


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 interventions¹

ORDERING INFORMATION

Product code	Wire type	Outer diameter	Overall length	Flexible tip length	Tip shape
RF*GE35185M	Standard	0.035" / 0.89 mm	180 cm	5 cm	Bolia curve 
RF*GE35188M	Standard	0.035" / 0.89 mm	180 cm	8 cm	
RF-GA18053M	Standard	0.018" / 0.46 mm	50 cm	3 cm	Bolia curve 
RF-GA18153M	Standard	0.018" / 0.46 mm	150 cm	3 cm	
RF-GA18183M	Standard	0.018" / 0.46 mm	180 cm	3 cm	
RF-GA18223M	Standard	0.018" / 0.46 mm	220 cm	3 cm	
RF-GA18263M	Standard	0.018" / 0.46 mm	260 cm	3 cm	
RF-GA25053M	Standard	0.025" / 0.64 mm	50 cm	3 cm	
RF-GA25123M	Standard	0.025" / 0.64 mm	120 cm	3 cm	
RF-GA25153M	Standard	0.025" / 0.64 mm	150 cm	3 cm	
RF-GA25183M	Standard	0.025" / 0.64 mm	180 cm	3 cm	
RF-GA25263M	Standard	0.025" / 0.64 mm	260 cm	3 cm	
RF-GA32123M	Standard	0.032" / 0.81 mm	120 cm	3 cm	
RF-GA32153M	Standard	0.032" / 0.81 mm	150 cm	3 cm	
RF-GA32183M	Standard	0.032" / 0.81 mm	180 cm	3 cm	
RF-GA32263M	Standard	0.032" / 0.81 mm	260 cm	3 cm	
RF-GA35053M	Standard	0.035" / 0.89 mm	50 cm	3 cm	
RF-GA35083M	Standard	0.035" / 0.89 mm	80 cm	3 cm	
RF-GA35123M	Standard	0.035" / 0.89 mm	120 cm	3 cm	
RF-GA35151M	Standard	0.035" / 0.89 mm	150 cm	1 cm	
RF*GA35153M	Standard	0.035" / 0.89 mm	150 cm	3 cm	
RF-GA35155M	Standard	0.035" / 0.89 mm	150 cm	5 cm	
RF-GA35158M	Standard	0.035" / 0.89 mm	150 cm	8 cm	
RF-GA35181M	Standard	0.035" / 0.89 mm	180 cm	1 cm	
RF*GA35183M	Standard	0.035" / 0.89 mm	180 cm	3 cm	
RF-GA35223M	Standard	0.035" / 0.89 mm	220 cm	3 cm	
RF-GA35261M	Standard	0.035" / 0.89 mm	260 cm	1 cm	
RF*GA35263M	Standard	0.035" / 0.89 mm	260 cm	3 cm	
RF-GA35303M	Standard	0.035" / 0.89 mm	300 cm	3 cm	
RF-GA38151M	Standard	0.038" / 0.97 mm	150 cm	1 cm	
RF*GA38153M	Standard	0.038" / 0.97 mm	150 cm	3 cm	
RF-GA38183M	Standard	0.038" / 0.97 mm	180 cm	3 cm	
RF-GA38223M	Standard	0.038" / 0.97 mm	220 cm	3 cm	
RF-GA38263M	Standard	0.038" / 0.97 mm	260 cm	3 cm	


Product code	Wire type	Outer diameter	Overall length	Flexible tip length	Tip shape
RF-GS18153M	Standard	0.018" / 0.46 mm	150 cm	3 cm	Straight 
RF-GS18183M	Standard	0.018" / 0.46 mm	180 cm	3 cm	
RF-GS18263M	Standard	0.018" / 0.46 mm	260 cm	3 cm	
RF-GS25123M	Standard	0.025" / 0.64 mm	120 cm	3 cm	
RF-GS25153M	Standard	0.025" / 0.64 mm	150 cm	3 cm	
RF-GS25183M	Standard	0.025" / 0.64 mm	180 cm	3 cm	
RF-GS25263M	Standard	0.025" / 0.64 mm	260 cm	3 cm	
RF-GS32123M	Standard	0.032" / 0.81 mm	120 cm	3 cm	
RF-GS32153M	Standard	0.032" / 0.81 mm	150 cm	3 cm	
RF-GS32183M	Standard	0.032" / 0.81 mm	180 cm	3 cm	
RF-GS32263M	Standard	0.032" / 0.81 mm	260 cm	3 cm	
RF-GS35123M	Standard	0.035" / 0.89 mm	120 cm	3 cm	
RF-GS35151M	Standard	0.035" / 0.89 mm	150 cm	1 cm	
RF*GS35153M	Standard	0.035" / 0.89 mm	150 cm	3 cm	
RF-GS35155M	Standard	0.035" / 0.89 mm	150 cm	5 cm	
RF-GS35158M	Standard	0.035" / 0.89 mm	150 cm	8 cm	
RF-GS35181M	Standard	0.035" / 0.89 mm	180 cm	1 cm	
RF-GS35183M	Standard	0.035" / 0.89 mm	180 cm	3 cm	
RF-GS35223M	Standard	0.035" / 0.89 mm	220 cm	3 cm	
RF-GS35261M	Standard	0.035" / 0.89 mm	260 cm	1 cm	
RF-GS35263M	Standard	0.035" / 0.89 mm	260 cm	3 cm	
RF-GS38151M	Standard	0.038" / 0.97 mm	150 cm	1 cm	
RF-GS38153M	Standard	0.038" / 0.97 mm	150 cm	3 cm	
RF-GS38183M	Standard	0.038" / 0.97 mm	180 cm	3 cm	
RF-GS38263M	Standard	0.038" / 0.97 mm	260 cm	3 cm	

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 duct¹

ORDERING INFORMATION

Product code	Wire type	Outer diameter	Overall length	Flexible tip length	Tip shape
NV-GA18153M	Standard	0.018" / 0.46 mm	150 cm	3 cm	
NV-GA25153M	Standard	0.025" / 0.64 mm	150 cm	3 cm	
NV-GA32153M	Standard	0.032" / 0.81 mm	150 cm	3 cm	
NV-GA32263M	Standard	0.032" / 0.81 mm	260 cm	3 cm	
NV-GA32403M	Standard	0.032" / 0.81 mm	400 cm	3 cm	
NV-GA35083M	Standard	0.035" / 0.89 mm	80 cm	3 cm	
NV-GA35123M	Standard	0.035" / 0.89 mm	120 cm	3 cm	
NV-GA35153M	Standard	0.035" / 0.89 mm	150 cm	3 cm	
NV-GA35183M	Standard	0.035" / 0.89 mm	180 cm	3 cm	
NV-GA35263M	Standard	0.035" / 0.89 mm	260 cm	3 cm	
NV-GA35403M	Standard	0.035" / 0.89 mm	400 cm	3 cm	
NV-GA35453M	Standard	0.035" / 0.89 mm	450 cm	3 cm	
NV-GA38153M	Standard	0.038" / 0.97 mm	150 cm	3 cm	
NV-PA18153M	Stiff	0.020" / 0.51 mm	150 cm	3 cm	
NV-PA18453M	Stiff	0.020" / 0.51 mm	450 cm	3 cm	
NV-PA25153M	Stiff	0.025" / 0.64 mm	150 cm	3 cm	
NV-PA25453M	Stiff	0.025" / 0.64 mm	450 cm	3 cm	
NV-PA35153M	Stiff	0.035" / 0.89 mm	150 cm	3 cm	
NV-PA35183M	Stiff	0.035" / 0.89 mm	180 cm	3 cm	
NV-PA35263M	Stiff	0.035" / 0.89 mm	260 cm	3 cm	
NV-PA35403M	Stiff	0.035" / 0.89 mm	400 cm	3 cm	
NV-PA38153M	Stiff	0.038" / 0.97 mm	150 cm	3 cm	
NV-GS18153M	Standard	0.018" / 0.46 mm	150 cm	3 cm	
NV-GS25123M	Standard	0.025" / 0.64 mm	120 cm	3 cm	
NV-GS25153M	Standard	0.025" / 0.64 mm	150 cm	3 cm	
NV-GS32153M	Standard	0.032" / 0.81 mm	150 cm	3 cm	
NV-GS32263M	Standard	0.032" / 0.81 mm	260 cm	3 cm	
NV-GS32403M	Standard	0.032" / 0.81 mm	400 cm	3 cm	
NV-GS35123M	Standard	0.035" / 0.89 mm	120 cm	3 cm	
NV-GS35153M	Standard	0.035" / 0.89 mm	150 cm	3 cm	
NV-GS35183M	Standard	0.035" / 0.89 mm	180 cm	3 cm	
NV-GS35263M	Standard	0.035" / 0.89 mm	260 cm	3 cm	
NV-GS35403M	Standard	0.035" / 0.89 mm	400 cm	3 cm	
NV-GS35453M	Standard	0.035" / 0.89 mm	450 cm	3 cm	
NV-GS38153M	Standard	0.038" / 0.97 mm	150 cm	3 cm	
NV-PS18453M	Stiff	0.020" / 0.51 mm	450 cm	3 cm	
NV-PS25453M	Stiff	0.025" / 0.64 mm	450 cm	3 cm	
NV-PS35083M	Stiff	0.035" / 0.89 mm	80 cm	3 cm	
NV-PS35153M	Stiff	0.035" / 0.89 mm	150 cm	3 cm	
NV-PS35183M	Stiff	0.035" / 0.89 mm	180 cm	3 cm	
NV-PS35263M	Stiff	0.035" / 0.89 mm	260 cm	3 cm	
NV-PS35403M	Stiff	0.035" / 0.89 mm	400 cm	3 cm	
NV-PS38153M	Stiff	0.038" / 0.97 mm	150 cm	3 cm	
NV-PS38183M	Stiff	0.038" / 0.97 mm	180 cm	3 cm	

Angled

Straight



AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declaratie de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
DM000334470	GHID PERIFERIC PENTRU CATETER	GLIDEWIRE ADVANTAGE TRACK™	PERIPHERAL GUIDEWIRE	RA*GB14181CM	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	Rg04-000020	26-01-2022	
DM000334472	GHID PERIFERIC PENTRU CATETER	GLIDEWIRE ADVANTAGE TRACK™	PERIPHERAL GUIDEWIRE	RA*GB18181CM	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	Rg04-000020	26-01-2022	
DM000334473	GHID PERIFERIC PENTRU CATETER	GLIDEWIRE ADVANTAGE TRACK™	PERIPHERAL GUIDEWIRE	RA*GB18301CM	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	Rg04-000020	26-01-2022	
DM000137359	GHID PENTRU CATETER	RADIFOCUS® GLIDEWIRE® ADVANTAGE™	GUIDE WIRE		Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-188	16-07-2018	
DM000334471	GHID PERIFERIC PENTRU CATETER	GLIDEWIRE ADVANTAGE TRACK™	PERIPHERAL GUIDEWIRE	RA*GB14301CM	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	Rg04-000020	26-01-2022	

✓ [Содержит\(\[NameMake\],_Glidewire\)](#) И Содержит([Producatorul],_Terumo) Очист



AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declarația de conformitate CE

Введите текст для поиска...										
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		Guide				Terumo				
DM000186955	GHID PENTRU CATETER	RADIFOCUS® GUIDE WIRE M	CATHETER GUIDE WIRE		Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000186953	GHID PENTRU CATETER	RADIFOCUS® GUIDE WIRE GT WITH GOLD COIL	CATHETER GUIDE WIRE		Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	
DM000196984	GHID PENTRU CATETER	Radifocus® Guidewire	M	NV-PS35263M	Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	
DM000196972	GHID PENTRU CATETER	Radifocus® Guidewire	M	NV-GS35453M	Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	
DM000196978	GHID PENTRU CATETER	Radifocus® Guidewire	M	NV-GS25153M	Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	
DM000196953	GHID PENTRU CATETER	Radifocus® Guidewire	M	NV-GA35183M	Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	
DM000196971	GHID PENTRU CATETER	Radifocus® Guidewire	M	NV-GS35403M	Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	
DM000196994	GHID PENTRU CATETER	Radifocus® Guidewire	M	NV-GS38153M	Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	
DM000196991	GHID PENTRU CATETER	Radifocus® Guidewire	M	NV-PS35183M	Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	
DM000196963	GHID PENTRU CATETER	Radifocus® Guidewire	M	NV-GA35403M	Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	

DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**

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

being the manufacturer of:

RADIFOCUS Glidewire Advantage

Guide Wire

Product : Catheter Guide Wire

declare that the above products of **Class IIa** 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, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), 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, February 10, 2020

(place and date of issue)


Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION



Appendix A – List of Code Number Structure

*

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

Character number	Character & Meaning	
1,2	Product name	RA : Radifocus Glidewire Advantage
3	Destination	* : export
4	Specifications of core wire	B : (distal) Ni-Ti/HALF STIFF + (proximal)Ni-Ti C : (distal)Ni-Ti/STIFF + (proximal)Ni-Ti F : (distal) Tip coil marker / Ni-Ti/STIFF + (proximal)Ni-Ti G : (distal)Tip coil marker /Ni-Ti/STIFF + (proximal) Stainless Steel
5	Tip configuration	A : angled type B : angled type S : straight type
6,7	O.D. of product	35 : φ0.89mm(0.035") 18 : φ0.46mm(0.018") 14 : φ0.36mm(0.014")
8,9	Overall length	18 : 180cm 26 : 260cm 30 : 300cm
10	Length of flexible portion at distal end	1 : 1cm 3 : 3cm 5 : 5cm
11	Length of hydrophilic coating	C : 25cm 3 : 30cm
12	Language for labeling	(blank): export M7 M: export M26

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 60116055 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, February 10, 2020

(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 0.032"		35 0.035"		38 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 other core types: 0.018" / 0.46 mm					
		32		35		38	
		0.032" / 0.81 mm		0.035" / 0.89 mm		0.038" / 0.97 mm	
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				
		220 cm	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					

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 018

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

Products included:

- Blood Bags
- Blood Donor Set
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet



Notified Body

M. Aihara

Date: 2019-12-23

M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Notified Body


M.Sc. M. Aihara



Date: 2019-12-23

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

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Notified Body

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M.Sc. M. Aihara

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Products included:

- Blood Bags
- Blood Donor Set
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet



Notified Body

M. Aihara

Date: 2019-12-23

M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Date: 2019-12-23

Notified Body


M.Sc. M. Aihara



Certificate

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
- Endoscopic Vessel Harvesting System
- 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

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.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29



Michihara

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

Certificate

**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 Catheter and Accessories
- 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.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29



Michihara

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

Certificate

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.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29



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