Climber



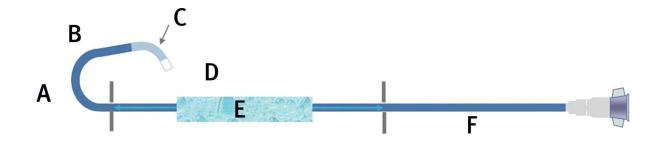
Climber® is a hydrophilic coated guiding catheter providing an ideal combination of dedicated hydrophilic coating, large inner lumen and passive back-up support.

Climber® offers a broad choice of curves to maximise your success.

Product Characteristics

- Smooth introduction and transition thanks to the large 0.071" inner diameter in 6 Fr and selective hydrophilic coating

- Tactile 1:1 torque control of the tip
 Encapsulated high strength flat braiding to provide high kink resistance, pushability and reliable back-up support
 Polyamide outer shaft material to enhance shape retention and minimal temperature softening during complex procedures
- Distal 7 cm uncoated part to ensure good grip at the ostium and controlateral wall support



- A Uncoated
- B Distal 7 cm
 C Intermediate Segment
 D Distal Soft Tip
 E Hydrophilic coating

F Uncoated Proximal 25 cm

General specifications

| Braiding | Ultra thin high strength 2 x 2 flat wire mesh pattern | | |
|-------------------------|---|--|--|
| Shaft Coating | Hydrophilic Coating | | |
| Shaft Material | Polyamide | | |
| Uncoated Distal Shaft | 7 cm | | |
| Uncoated Proximal Shaft | 25 cm | | |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Side Holes | Code |
|-----------------|---------------|-----------------------------|----------------|------------|-------------|
| | | | | | |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | | 0 | GC-P5TR450N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0,058 in 1.47 mm | - | 0 | GC-P5RM000N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | | 0 | GC-P5JR300N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | - | 0 | GC-P5RD000N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | | 0 | GC-P5TR350N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | - | 0 | GC-P5RL350N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | | 0 | GC-P5RL400N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | - | 0 | GC-P5TR500N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | | 0 | GC-P5TR300N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | - | 0 | GC-P5RK000N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Radial TIG 4.0 | 0 | GC-P5TR400N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | ? | 0 | GC-P5IM000N |
| | | | | | |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Side Holes | Code |
|-----------------|---------------|-----------------------------|------------------|------------|-------------|
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Left 3.5 | 0 | GC-P5JL350N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Left 3 | 0 | GC-P5JL300N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Left 4.5 | 0 | GC-P5JL450N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Left 4 | 0 | GC-P5JL400N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Left 5 | 0 | GC-P5JL500N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Left 6 | 0 | GC-P5JL600N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Multipurpose | 0 | GC-P5MP000N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Bypass Left | 0 | GC-P5BP010N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Bypass Right | 0 | GC-P5BP020N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Side Holes | Code |
|-----------------|---------------|-----------------------------|--|------------|-------------|
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Left Coronary 3.25 | 0 | GC-P5EB320N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Left Coronary 3.5 | 0 | GC-P5EB350N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Left Coronary 3.75 | 0 | GC-P5EB370N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Left Coronary 3 | 0 | GC-P5EB300N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Left Coronary 4.25 | 0 | GC-P5EB420N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Left Coronary 4.5 | 0 | GC-P5EB450N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Left Coronary 4.75 | 0 | GC-P5EB470N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Left Coronary 4 | 0 | GC-P5EB400N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Side Holes | Code |
|-----------------|---------------|-----------------------------|---|------------|-------------|
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Left Coronary 5 | 0 | GC-P5EB500N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Right Coronary 3.5 | 0 | GC-P5XR350N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Right Coronary 3.75 | 0 | GC-P5XR370N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Right Coronary 3 | 0 | GC-P5XR300N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Right Coronary 4.25 | 0 | GC-P5XR420N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Right Coronary 4.5 | 0 | GC-P5XR450N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Extra BackUp For Right Coronary 4 | 0 | GC-P5XR400N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Hockey Stick | 0 | GC-P5HS000N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Amplatz Right 2 | 0 | GC-P5AR200N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Side Holes | Code |
|-----------------|---------------|-----------------------------|-------------------|------------|-------------|
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Right 3.5 | 0 | GC-P5JR350N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Right 4.5 | 0 | GC-P5JR450N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Right 4 | 0 | GC-P5JR400N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Right 5 | 0 | GC-P5JR500N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Judkins Right 6 | 0 | GC-P5JR600N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Amplatz Right 1 | 0 | GC-P5AR100N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Amplatz Left 0.75 | 0 | GC-P5AL070N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Amplatz Left 1.5 | 0 | GC-P5AL150N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Amplatz Left 1 | 0 | GC-P5AL100N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Side Holes | Code |
|-----------------|---------------|-----------------------------|----------------|------------|-------------|
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Amplatz Left 2 | 0 | GC-P5AL200N |
| 5 Fr 1.76 mm | 100 cm | 5 Fr 0.058 in 1.47 mm | Amplatz Left 3 | 0 | GC-P5AL300N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 0 | GC-P6JR300N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 0 | GC-P6RD000N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 0 | GC-P6TR300N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 0 | GC-P6TR350N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 0 | GC-P6TR450N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 0 | GC-P6TR500N |
| 6 Fr 2,08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 2 | GC-P6TR300A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 2 | GC-P6TR350A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 2 | GC-P6TR450A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 2 | GC-P6TR500A |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Side Holes | Code |
|-----------------|---------------|----------------------------|------------------|------------|-------------|
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | 2 | GC-P6JR300A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Radial TIG 4.0 | 0 | GC-P6TR400N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Radial TIG 4.0 | 2 | GC-P6TR400A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | ? | 0 | GC-P6IM000N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | ? | 2 | GC-P6IM000A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 3.5 | 0 | GC-P6JL350N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 3.5 | 2 | GC-P6JL350A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 3 | 0 | GC-P6JL300N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 3 | 2 | GC-P6JL300A |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Side Holes | Code |
|-----------------|---------------|----------------------------|------------------|------------|-------------|
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 4.5 | 0 | GC-P6JL450N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 4.5 | 2 | GC-P6JL450A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 4 | 0 | GC-P6JL400N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 4 | 2 | GC-P6JL400A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 5 | 0 | GC-P6JL500N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 5 | 2 | GC-P6JL500A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 6 | 0 | GC-P6JL600N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 6 | 2 | GC-P6JL600A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Multipurpose | 0 | GC-P6MP000N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Side Holes | Code |
|-----------------|---------------|----------------------------|--|------------|-------------|
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Multipurpose | 2 | GC-P6MP000A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Bypass Left | 0 | GC-P6BP010N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Bypass Left | 2 | GC-P6BP010A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Bypass Right | 0 | GC-P6BP020N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Bypass Right | 2 | GC-P6BP020A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 3.25 | 0 | GC-P6EB320N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 3.25 | 2 | GC-P6EB320A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 3.5 | 0 | GC-P6EB350N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 3.5 | 2 | GC-P6EB350A |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Side Holes | Code |
|-----------------|---------------|----------------------------|--|------------|-------------|
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 3.75 | 0 | GC-P6EB370N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 3.75 | 2 | GC-P6EB370A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 3 | 0 | GC-P6EB300N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 3 | 2 | GC-P6EB300A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 4.25 | 0 | GC-P6EB420N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 4.25 | 2 | GC-P6EB420A |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 4.5 | 0 | GC-P6EB450N |
| 6 Fr 2.08 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Extra BackUp For Left Coronary 4.5 | 2 | GC-P6EB450A |



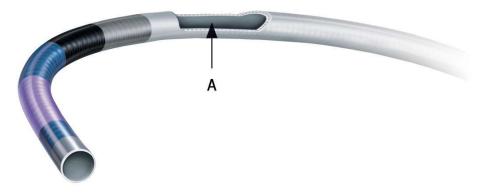


Guiding Catheter

Heartrail® II Guiding Catheter is designed for the introduction of interventional devices and/or guidewires and for the delivery of contrast media into the coronary or peripheral vascular systems.

Product Characteristics

- Terumo's Zone Technology engineered for reliable back-up support
 Large inner lumen diameter 6 Fr (0.071"- 1.80 mm) enables kissing Balloon Technique
 PTFE inner layer for smooth device delivery
 5 in 6 system enables to increase back up force without changing outer sizes of guiding catheter
- IKARI shapes designed for optimal backup support in TRI procedures



A PTFE inner layer for friction reduction

General specifications

| Braiding | High strength flat wire mesh pattern |
|----------------------------|--------------------------------------|
| Inner Layer | Polytetrafluoroethylene - PTFE |
| Maximum Injection Pressure | 4826 kPa / 700 psi |
| Side Holes | 0 |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Code |
|-----------------|---------------|----------------------------|---------------------------------|-------------|
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | - | GC-K5TR500N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | ر | GC-K5IMA10N |
| 5 Fr 1,73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Judkins Left 3.5 | GC-K5JL350N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Judkins Left 4.5 | GC-K5JL450N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Judkins Left 4 | GC-K5JL400N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Judkins Left 5 | GC-K5JL500N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Judkins Left 6 | GC-K5JL600N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Multipurpose | GC-K5MP030N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Backup For Left Coronary 3.5 | GC-K5BL350N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Backup For Left Coronary 3 | GC-K5BL300N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Code |
|-----------------|---------------|----------------------------|---|--------------|
| 5 Fr | 100 cm | 5 Fr 0.059 in | | GC-K5BL450N |
| 1,73 mm | 200 0.11 | 1.5 mm | Backup For Left Coronary 4.5 | 33 132 130 1 |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Packup For Left Coronany 4 | GC-K5BL400N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Backup For Left Coronary 4 Bypass Left | GC-K5BP010N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Bypass Right | GC-K5BP020N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Ikari-Curve Left 3.5 | GC-K5IL350N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Ikari-Curve Left 4 | GC-K5IL400N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Ikari-Curve Right 1.5 | GC-K5IR150N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Ikari-Curve Right 2 | GC-K5IR200N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Amplatz Right 2 | GC-K5AR020N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Judkins Right 3.5 | GC-K5JR350N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Code |
|-----------------|---------------|----------------------------|-------------------|--------------|
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Judkins Right 4.5 | GC-K5JR450N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Judkins Right 4 | GC-K5JR400N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Judkins Right 5 | GC-K5JR500N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Judkins Right 6 | GC-K5JR600N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Amplatz Right 1 | GC-K5AR010N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Amplatz Left 1 | GC-K5AL010N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Amplatz Left 2 | GC-K5AL020N |
| 5 Fr 1.73 mm | 100 cm | 5 Fr 0.059 in 1.5 mm | Amplatz Left 3 | GC-K5AL030N |
| 5 Fr 1.73 mm | 120 cm | 5 Fr 0.059 in 1.5 mm | 5 In 6 System | GC-K5ST012NQ |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | GC-K6DR060N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Code |
|-----------------|---------------|-------------------------------------|------------------|-------------|
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in - GC-K6T 1.8 mm | | GC-K6TR500N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | GC-K6DR040N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | GC-K6MP020N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | GC-K6BL250N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | GC-K6ER400N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | GC-K6DR050N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | - | GC-K6MP010N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 3.5 | GC-K6JL350N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 3 | GC-K6JL300N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 4.5 | GC-K6JL450N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 4 | GC-K6JL400N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Code |
|-----------------|---------------|----------------------------|---------------------------------|-------------|
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 5 | GC-K6JL500N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Left 6 | GC-K6JL600N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Multipurpose | GC-K6MP030N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Backup For Left Coronary 3.5 | GC-K6BL350N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Backup For Left Coronary 3 | GC-K6BL300N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Backup For Left Coronary 4.5 | GC-K6BL450N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Backup For Left Coronary 4 | GC-K6BL400N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Backup For Right Coronary 3.5 | GC-K6BR350N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Backup For Right Coronary | GC-K6BR400N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Bypass Right | GC-K6BP020N |
| | | | Dypuss riigiit | |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Code |
|-----------------|---------------|----------------------------|-----------------------|-------------|
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Ikari-Curve Left 3.5 | GC-K6IL350N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Ikari-Curve Left 3 | GC-K6IL300N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Ikari-Curve Left 4.5 | GC-K6lL450N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Ikari-Curve Left 4 | GC-K6IL400N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Ikari-Curve Right 1.5 | GC-K6IR150N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Ikari-Curve Right 1 | GC-K6IR100N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | lkari-Curve Right 2 | GC-K6IR200N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | IMA 1 | GC-K6IMA10N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Amplatz Right 2 | GC-K6AR020N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Code |
|-----------------|---------------|----------------------------|-------------------|-------------|
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Right 3.5 | GC-K6JR300N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Right 3.5 | GC-K6JR350N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Right 4.5 | GC-K6JR450N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Right 4 | GC-K6JR400N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Right 5 | GC-K6JR500N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Judkins Right 6 | GC-K6JR600N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Amplatz Right 1 | GC-K6AR010N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Amplatz Left 1 | GC-K6AL010N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Amplatz Left 2 | GC-K6AL020N |
| 6 Fr 2.06 mm | 100 cm | 6 Fr 0.071 in 1.8 mm | Amplatz Left 3 | GC-K6AL030N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Code |
|-----------------|---------------|-----------------------------|------------------------------|-------------|
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | · | GC-K7TR500N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | 2 | GC-K7IMA10N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Judkins Left 3.5 | GC-K7JL350N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Judkins Left 4.5 | GC-K7JL450N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Judkins Left 4 | GC-K7JL400N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Judkins Left 5 | GC-K7JL500N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Judkins Left 6.0 | GC-K7JL600N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Multipurpose | GC-K7MP030N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Backup For Left Coronary 3.5 | GC-K7BL350N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Backup For Left Coronary 3 | GC-K7BL300N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Code |
|-----------------|---------------|-----------------------------|------------------------------|-------------|
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Backup For Left Coronary 4.5 | GC-K7BL450N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Backup For Left Coronary 4 | GC-K7BL400N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Bypass Right | GC-K7BP020N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Ikari-Curve Left 3.5 | GC-K7IL350N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | lkari-Curve Left 4 | GC-K7IL400N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Ikari-Curve Right 1,5 | GC-K7IR150N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | lkari-Curve Right 2 | GC-K7IR200N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Amplatz Right 2 | GC-K7AR020N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Judkins Right 3.5 | GC-K7JR350N |

| Outer Diameter | Usable Length | Inner Diameter | Shape | Code |
|-----------------|---------------|-----------------------------|-------------------|-------------|
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Judkins Right 4.5 | GC-K7JR450N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Judkins Right 4 | GC-K7JR400N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Judkins Right 5 | GC-K7JR500N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Judkins Right 6.0 | GC-K7JR600N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Amplatz Right 1 | GC-K7AR010N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Amplatz Left 1 | GC-K7AL010N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Amplatz Left 2 | GC-K7AL020N |
| 7 Fr 2.36 mm | 100 cm | 7 Fr 0.081 in 2.06 mm | Amplatz Left 3 | GC-K7AL030N |

Van der Waalspark 22, 9351 VC Leek, The Netherlands +31 (0) 85 0073 000 | info@wellinq.com | www.wellinq.com

Declaration of Conformity to Directive 93/42/EEC concerning Medical Devices FORM 140-05 / DCR 13-459
Document: RA DoC-020 Rev. 10 / DCR 19-100
Climber Guiding Catheter

Page 1 of 1

DECLARATION OF CONFORMITY to Directive 93/42/EEC concerning Medical Devices

Name of Product: Climber M Guiding Catheter

Legal (labelled) PendraCare International B.V.

Manufacturer: Van der Waalspark 22

9351 VC Leek The Netherlands

Dutch Chamber of Commerce - Registration Number 02086018

Declaration:

I hereby declare that the medical device specified in this declaration conforms to the provisions of the *current* European Council (EC) Directive 93/42/EEC of June 14, 1993 concerning Medical Devices and therefore bears the CE mark of conformity on its labelling in combination with the Notified Body Identification number 0344 of DEKRA Certification B.V., Arnhem, The Netherlands.

- The product conforms to the applicable Essential Requirements for Safety and Performance per current Directive 93/42/EEC, Annex I: "Essential Requirements",
- The device classification (i.e., Class III) has been determined per *current* Directive 93/42/EEC, Annex IX: Classification Criteria,
- The appropriate Conformity Assessment module per article 11 of the *current* Directive 93/42/EEC, i.e., Annex II (4) has been followed as indicated on the "EC Design-Examination" Certificate (2020764DE02) in combination with this Declaration of Conformity,
- PendraCare's Quality Management System (QMS) fulfils the requirements described in the *current* Directive 93/42/EEC and EN-ISO 13485: 2016 as evidenced by the "CE Marking of Conformity" Certificate [2020764CE01- Full Quality Assurance System per Annex II excluding (4)] and its accompanying Certification Notice (2020764CN) and by the Certificate of Registration (2086817). The specified medical device falls within the scope of PendraCare's QMS as indicated in the certificates.

GMDN: GMDN Term*: Vascular Guide Catheter GMDN Code*: 17846

* per GMDN agency database

Valid until: This Declaration of Conformity is valid until **November 1, 2023**, i.e., the validity date

indicated on the CE-marking of Conformity Certificate and the product's EC Design-

Examination Certificate.

Reference: RA DoCa-020 Rev. 10 - Annex to the Declaration of Conformity.

Place of issue: Leek, The Netherlands

Date: 2019-03-26

Declared by:

J. van der Kuil

Manager Quality Assurance & Regulatory Affairs





No.DOC-DQ010-0751

Rev.11

DECLARATION OF CONFORMITY

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

being the manufacturer of:

Heartrail II

Guiding Catheter

Product: Catheter, intravascular, guiding

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 60108681 0001) under the supervision of TÜV Rheinland Product Safety 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



No.DOC-DQ010-0751

Rev.11

Appendix A - List of Code Number Structure

| G | С | - | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|----|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

| Character number | Characters | Meanings |
|------------------|--|--|
| 1-2 | Product | GC: Guiding catheter |
| 3 | Destination | - : for export and domestic |
| 4 | Trade Name | K: for coronary use |
| | | P: for peripheral use |
| | | F: for coronary use (for Asia and Australia) |
| 5 | Catheter size | 5: 5Fr 6:6Fr 7:7Fr |
| 6 | Type of Catheter | A~Z 0~9 |
| 7 | (shape type) | A~Z 0~9 |
| 8 | Tip shape (length, radius, angle and other | A~Z 0~9 |
| 9 | factors of curve to make shape) | A~Z 0~9 |
| 10 | Effective catheter length | R:85cm, 0:100cm, 2:120cm, |
| 11 | Side hole | Number of side holes: 0 1 2 3 |
| | | Character : N 1 A K |
| 12 | Types of raw material | Q: 5Fr. ST, catheter length 120cm type |
| | | NA: others |

CERTIFICATE

Number: 2086817

The management system of the organization(s) and locations mentioned on the addendum belonging to:

PendraCare International B.V.

Van der Waalspark 22 9351 VC Leek The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

Design and development, manufacturing and distribution of Cardiovascular catheters and Urodynamic Catheters

Certificate expiry date: 1 January 2023
Certificate effective date: 1 January 2020
Certified since: 1 January 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum

DEKRA Certification B.V.

B.T.M. Holtus Managing Director J.A. van Vugt Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2086817

The management system of the organization(s) and/or location(s) of:

PendraCare International B.V.

Van der Waalspark 22 9351 VC Leek The Netherlands

Certified organization(s) and/or locations:

Different scope

PendraCare International B.V. Kamerlingh-Onnesstraat 6 9351 VD Leek

The Netherlands

Warehouse

PendraCare International B.V.

Stevinstraat 8 9351 VD Leek The Netherlands Design and Development

PendraCare International B.V Kamerlingh-Onnesstraat 10 9351 VD Leek

The Netherlands

Design and Development

Addendum expiry date: 1 January 2023 Addendum effective date: 1 January 2020

EC CERTIFICATE

Number: 2020764CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

PendraCare International B.V.

Van der Waalspark 22 9351 VC Leek The Netherlands

For the product category(ies)

Cardiovascular catheters

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2020764CN, initially dated 30 June 2003 Addendum, initially dated 30 June 2003

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024 Issued for the first time: 30 June 2003 Reissued: 1 January 2021

DEKRA Certification B.V.

B.T.M. Holtus Managing Director J.A. van Vugt Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2020764CE01

CE MARKING OF CONFORMITY MEDICAL DEVICES

Cardiovascular catheters

Issued to:

PendraCare International B.V.

Van der Waalspark 22 9351 VC Leek The Netherlands

This certificate covers the following product(s):

Intravascular Guiding Catheter (GMDN code 17846) (Class III)

- Primum Hydrophilic Guiding Catheter
- Serpia Hydrophilic Guiding Catheter
- Convey Guiding Catheter
- Climber Guiding Catheter

Angiographic Catheter (GMDN code 10688) (Class III)

- Pointer Angiographic Catheter
- Angiodyn Angiographic Catheter
- Revealer Angiographic Catheter

Initial date: 30 June 2003

Revision date: 6 November 2018

DEKRA Certification B.V.

B.T.M. Holtus Managing Director J.A. van Vugt Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396



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 att

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

Prifizierung 55

Notified Body

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.

TÜVRheinlan



Doc. 1/2, Rev.0

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

TÜVRhei Notified Body

M.Sc. M. Aihara

Date: 2019-12-23



Doc. 2/2, Rev.0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.: Report No.:

HD 60145252 0001

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



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



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

TÜVRheinland



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





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