

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



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## 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				

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



# **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

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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

# **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



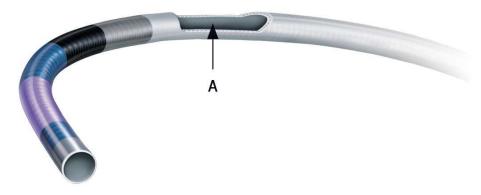


## **Guiding Catheter**

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	2	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

100 cm	5 Fr		
	0.059 in 1.5 mm	Backup For Left Coronary 4.5	GC-K5BL450N
100 cm	5 Fr 0.059 in 1.5 mm	Backup For Left Coronary 4	GC-K5BL400N
100 cm	5 Fr 0.059 in 1.5 mm	Bypass Left	GC-K5BP010N
100 cm	5 Fr 0.059 in 1.5 mm	Bypass Right	GC-K5BP020N
100 cm	5 Fr 0.059 in 1.5 mm	Ikari-Curve Left 3.5	GC-K5IL350N
100 cm	5 Fr 0.059 in 1.5 mm	Ikari-Curve Left 4	GC-K5IL400N
100 cm	5 Fr 0.059 in 1.5 mm	Ikari-Curve Right 1.5	GC-K5IR150N
100 cm	5 Fr 0.059 in 1.5 mm	Ikari-Curve Right 2	GC-K5IR200N
100 cm	5 Fr 0.059 in 1.5 mm		GC-K5AR020N
100 cm	5 Fr 0.059 in 1.5 mm		GC-K5JR350N
	100 cm  100 cm  100 cm  100 cm	100 cm	100 cm  1.5 Fr  0.059 in  1.5 mm  Backup For Left Coronary 4  100 cm  0.059 in  1.5 mm  Bypass Left  100 cm  0.059 in  1.5 mm  Ikari-Curve Left 3.5  100 cm  0.059 in  1.5 mm  Ikari-Curve Right 1.5  100 cm  0.059 in  1.5 mm  Ikari-Curve Right 2  100 cm  0.059 in  1.5 mm  Ikari-Curve Right 2

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 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
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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	lkari-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-K6IL450N
6 Fr 2.06 mm	100 cm	6 Fr 0.071 in 1.8 mm	lkari-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	Ikari-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	?	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-K7lL400N
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	Ikari-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

## Climber

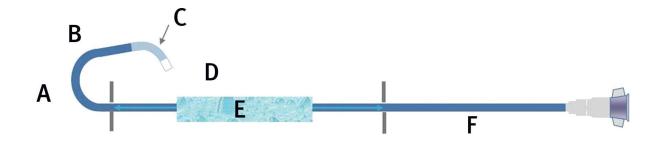


Climber® is a hydrophilic coated guiding catheter providing an ideal combination of dedicated hydrophilic coating, large inner lumen and passive back-up support.

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
outer biameter	osable Length	initer blameter	Shape	orac rioles	Couc
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	2	0	GC-P5IM000N
			IMA		

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



#### REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

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

Введите текст дл	оп к	иска								
Nr (	S)	Denumire 💟	Den.comerc 📀	Model 📀	Nr. catalog 🛇	Tara 📀	Producatorul 🛇	Reprezentant 📀	Ordin 📀	Data (
	8	7	Climber	₹	7	7	7	7	₽	-
OM000197229		GHID PENTRU CATETER PTCA	Climber®	PTCA guiding catheter		Olanda	PENDRACARE INTERNATIONAL B.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019
OM000197145		GHID PENTRU CATETER PTCA	Climber®	PTCA guiding catheter	GC-P6JR450N	Olanda	PENDRACARE INTERNATIONAL B.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019
0M000197311		GHID PENTRU CATETER PTCA	Climber®	PTCA guiding catheter	GC-P8JR400N	Olanda	PENDRACARE INTERNATIONAL B.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019
DM000197265		GHID PENTRU CATETER PTCA	Climber®	PTCA guiding catheter	GC-P7JL350A	Olanda	PENDRACARE INTERNATIONAL B.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019
M000197181		GHID PENTRU CATETER PTCA	Climber®	PTCA guiding catheter	GC-P6JL350A	Olanda	PENDRACARE INTERNATIONAL B.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019
M000197138		GHID PENTRU CATETER PTCA	Climber®	PTCA guiding catheter	GC-P6JL400N	Olanda	PENDRACARE INTERNATIONAL B.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019
M000197308		GHID PENTRU CATETER PTCA	Climber®	PTCA guiding catheter	GC-P8JL600N	Olanda	PENDRACARE INTERNATIONAL B.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019
M000197353		GHID PENTRU CATETER PTCA	Climber®	PTCA guiding catheter	GC-P8JR600A	Olanda	PENDRACARE INTERNATIONAL B.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019
M000197342		GHID PENTRU CATETER PTCA	Climber®	PTCA guiding catheter	GC-P8JL300A	Olanda	PENDRACARE INTERNATIONAL B.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019
M000197285		GHID PENTRU CATETER PTCA	Climber®	PTCA guiding catheter	GC-P7XR300N	Olanda	PENDRACARE INTERNATIONAL B.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019



#### REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

