



PEG Kit

Used for percutaneous endoscopic gastrostomy placement and to provide enteral nutrition to the patient requiring nutritional support



1 Introducer needle – Big needle
1 Scalpel
1 5ml Syringe with Needle

- 1 25 Gauge needle Small needle
- 1 Drape

1 Cable tie

Art. No.	Size (Fr/CH)	Remarks
PEG-20	20	
PEG-20+SN+SC	20	With Snare and Scissors
PEG-24	24	
PEG-24+SN+SC	24	With Snare and Scissors

PEG Exchange Catheter

For artificial feeding

100% Silicone Balloon Catheter Balloon 20ml With silicone support – open tip Boxes of 10 pcs.



Art. No.	Size (Fr/CH)	Usable Length (cm)
REPL-CAT 18	18	19
REPL-CAT 20	20	19
REPL-CAT 22	22	19
REPL-CAT 24	24	19





Multiband Ligator

Barrel with 6 bands

Used for endoscopic ligation of esophageal varices at or above gastroesophageal junction

Fits on wide range of endoscopes Second last band light colour Barrel with 7 bands available

Standard Band Ligator

Requires 9.5 to 11.2 mm Endoscope diameter

Paediatric Band Ligator

Requires 8.0 to 9.5 mm Endoscope diameter





Art. No. Description Standard SGK-6 Set incl. Applicator barrel, thread puller and flushing needle SGB-6 Barrel and thread puller only Paediatric SGK-6-S Set incl. Applicator barrel, thread puller and flushing needle SGB-6-S Barrel and thread puller only

Multiband Ligator Colonic

Used for endoscopic ligation of colonic varices

Fits on wide range of endoscopes Second last band light colour

Band Ligator Colonic Set contains:

Applicator, Barrel loaded with 6 bands or Barrel loaded with 7 bands
Atraumatic plastic hook with tube Flushing needle blunt tip Second last band with light colour Requires 12.8 to 13.5 mm Endoscope diameter

Barrel Colonic contains:

Barrel loaded with 6 bands or Barrel loaded with 7 bands Atraumatic plastic hook with tube



	Art. No.	Description
Band Ligator	SBLS-6-C	Multiband Ligator Colonic Set incl. Applicator barrel, thread puller and flushing needle
	SBL-6-C	Multiband Ligator Colonic Barrel and thread puller only
Barrel Colonic	SBLS-7-C	Multiband Ligator Colonic Set incl. Applicator barrel, thread puller and flushing needle
	SBL-7-C	Multiband Ligator Colonic Barrel and thread puller only







Product Service

EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 106138 0002 Rev. 00

Manufacturer:

Marflow AG

Soodstrasse 57 8134 Adliswil, Zurich **SWITZERLAND**

Product Category(ies): Class IIb

Double J stent & set

Class IIa

PCN catheter & set Ureteral catheter Malecot catheter

Re-entry malecot catheter Suprapubic catheter Braided shaft catheter Dual lumen catheter Facial dilator

Amplatz dilator & set Ureteral dilator & set Ureteral balloon dilator Double J stent & set Mono J stent

Endopyelotomy stent Guidewire IP Needle

Chiba needle Stone basket Perk basket

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

IND20190101

Valid from:

2020-04-03

Valid until:

2024-05-26

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. <u>Tracey WALTHER</u>, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunaustrasse 17, 8002 Zürich, identified by identity card.

Zürich, 8th April 2020

BK no. 1027ff Fee CHF 20.00



NOTARIAT ENGE-ZÜRICH

Andreas Bachmann, Notary Public

APOSTILLE (Convention de la Haye du 5 octobre 1961) 1. Land: Schweizerische Eidgenossenschaft, Kanton Zürich Country: Swiss Confederation, Canton of Zürich Diese öffentliche Urkunde / This public document 2. ist unterschrieben von Andreas Bachmann has been signed by 3. in seiner Eigenschaft als **Notary Public** acting in the capacity of 4. sie ist versehen mit dem Stempel/Siegel des (der) - bears the stamp/seal of Notariat Enge - Zürich Kanton Zürich Bestätigt / Certified 6. am / the 08.04.2020 5. In / at 8090 Zürich / Zurich 7. durch die Staatskanzlei des Kantons Zürich by the Chancellery of State of the Canton of Zurich 1179274/2020 8. unter Nr. / under Nº 10. Unterschrift / Signature Stempel/Siegel, Stamp/seal S. Overkott







Certificate

No. Q5 106138 0001 Rev. 00

Holder of Certificate: Marflow AG

Soodstrasse 57 8134 Adliswil, Zurich SWITZERLAND

Facility(ies): Marflow AG

Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

Certification Mark:



Scope of Certificate: Design and Development, Manufacture and Supply of Medical

Disposables, Surgical Tools, Equipment & Accessories in the Field of Urology, Gastroenterology, Radiology, Gynaecology

& Cardiology.

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

IND20190101

Valid from:

2020-04-03

Valid until:

2023-04-02

Date.

2020-04-03

Christoph Dicks

Head of Certification/Notified Body

T. Walter

Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. Tracey WALTHER, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunaustrasse 17, 8002 Zürich, identified by identity card.

Zürich, 8th April 2020 BK no. 1027ff Fee CHF 20.00

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Andreas Bachmann, Notary Public

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has been signed by

Andreas Bachmann

3. in seiner Eigenschaft als

acting in the capacity of

Notary Public

4. sie ist versehen mit dem Stempel/Siegel des (der) - bears the stamp/seal of

Notariat Enge - Zürich Kanton Zürich

Bestätigt / Certified

- 5. In / at 8090 Zürich / Zurich
- 6. am / the 08.04.2020
- 7. durch die Staatskanzlei des Kantons Zürich by the Chancellery of State of the Canton of Zurich
- 8. unter Nr. / under N°

1179275/2020

Stempel/Siegel, Stamp/seal

10. Unterschrift Signature

S. Overkott





Product Service

EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 106138 0003 Rev. 00

Manufacturer:

Marflow AG

Soodstrasse 57 8134 Adliswil, Zurich SWITZERLAND

Product

Class Is

Category(ies):

Urine bag connector

Penile clamp Evacuator

IUI catheter without syringe

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

IND20190101

Valid from: Valid until:

2020-04-03 2024-05-26

Date,

Page 1 of 2

2020-04-03

Christoph Dicks

Head of Certification/Notified Body

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