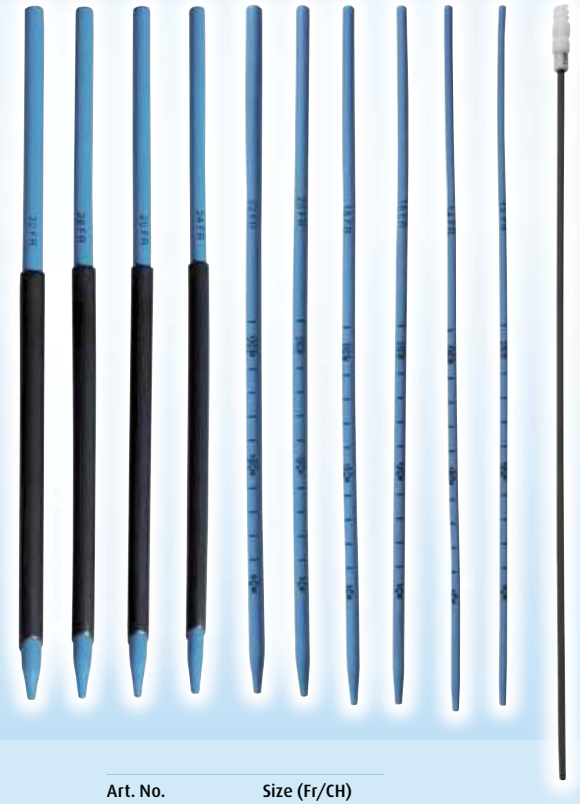
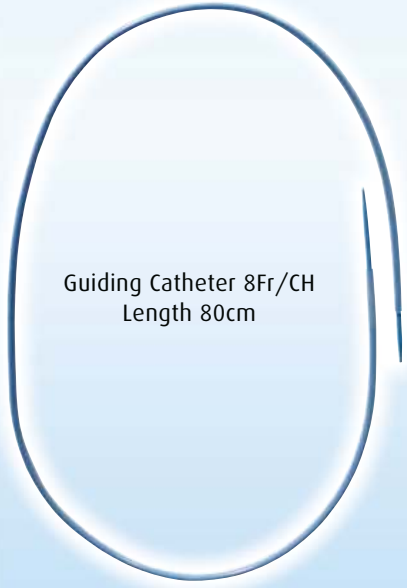
Amplatz Renal Dilation Set

Hydrophilic coated

Used for progressive dilation of the nephrostomy tract prior to percutaneous stone removal. Radiopaque dilators.





Guiding Catheter 8Fr/CH
Length 80cm

Art. No.	Size (Fr/CH)
ARDS 8/30	8 to 30

Digitally signed by Bunic Gheorghe
Date: 2022.03.01 12:56:38 EET
Reason: MoldSign Signature
Location: Moldova

Class IIa device – for single use only

Amplatz Renal Dilators

Hydrophilic coated

Used for progressive dilation of the nephrostomy tract prior to percutaneous stone removal. Radiopaque dilators.

Single

Art. No.	Size (Fr/CH)	Length (cm)
RD 18	18	30
RD 20	20	30
RD 22	22	30
RD 24	24	30
RD 26	26	30
RD 28	28	30
RD 30	30	30

Amplatz Sheath

Hydrophilic coated

Used during renal dilatation to provide atraumatic working tracks after removal of the dilator.

Art. No.	Size (Fr/CH)	Length (cm)
AM 10	10	30
AM 24	24	17
AM 26	26	17
AM 28	28	17
AM 30	30	17

Class IIa device – for single use only

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

Class IIa device – non sterile – for single use 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

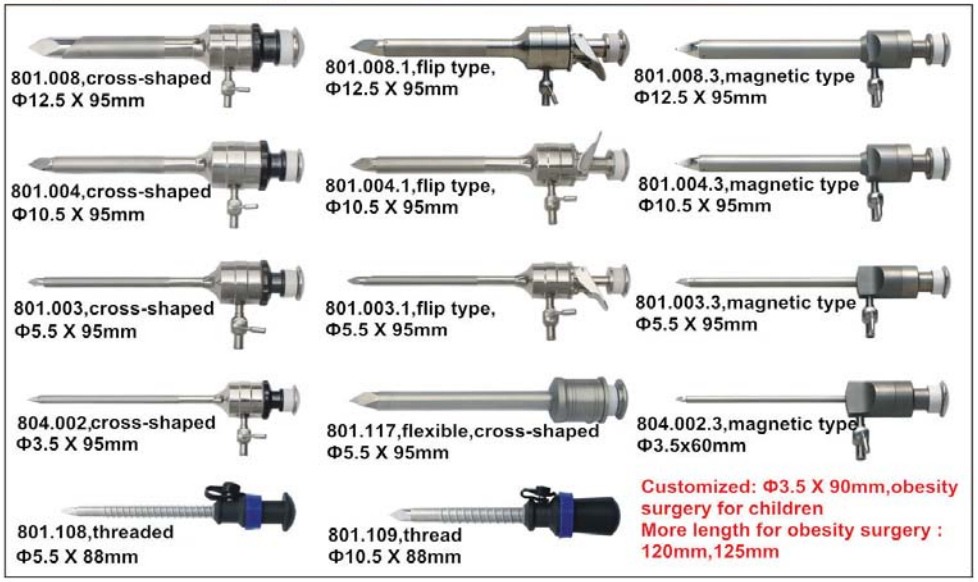
	Art. No.	Description
Band Ligator	**SBLS-6-C**	Multiband Ligator Colonic Set incl. Applicator barrel, thread puller and flushing needle
	SBL-6-C	Multiband Ligator Colonic Barrel and thread puller only
Barrel Colonic	**SBLS-7-C**	Multiband Ligator Colonic Set incl. Applicator barrel, thread puller and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

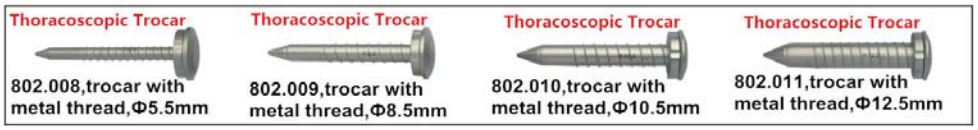
Class IIa device – non sterile – for single use only

Laparoscopic Instruments

Laparoscope

Trocar and Sealing Cap

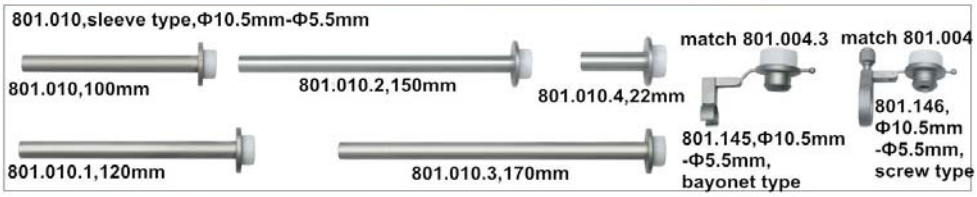




Customized Length:
Φ3.5/Φ5.5/Φ10.5/Φ12.5x90mm/120mm/125mm

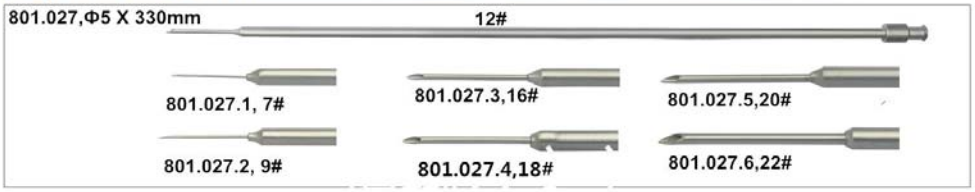
Laparoscopic Instruments

Reducer



Veress Needle

Aspiration Needle



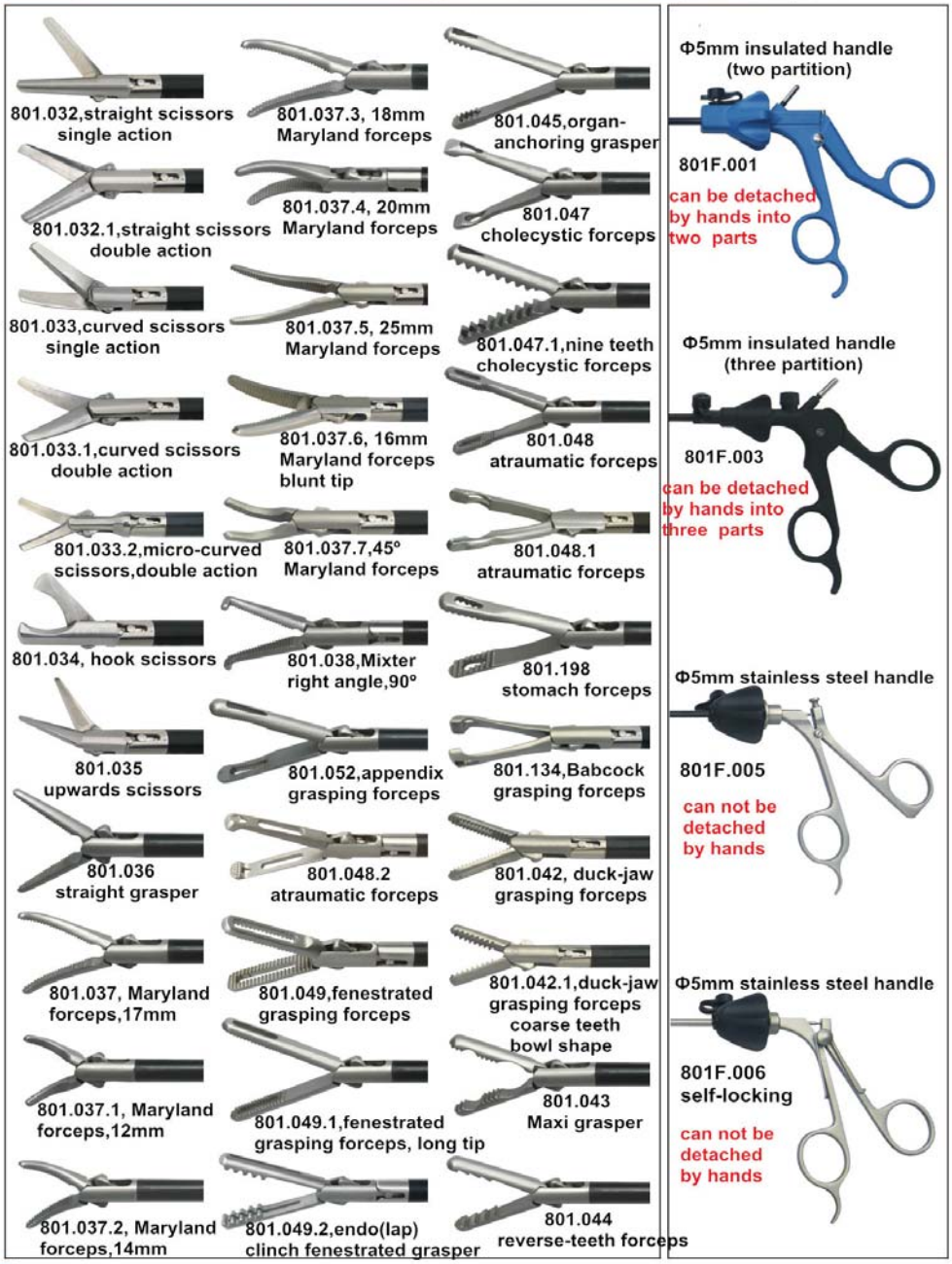
Bile Duct Knife

Monopolar HF Electrode-Electrode, monopolar, with insulated sheath, L-Hook

Customize Length:
5mmx360mm/410mm/430mm/440mm/450mm/460mm

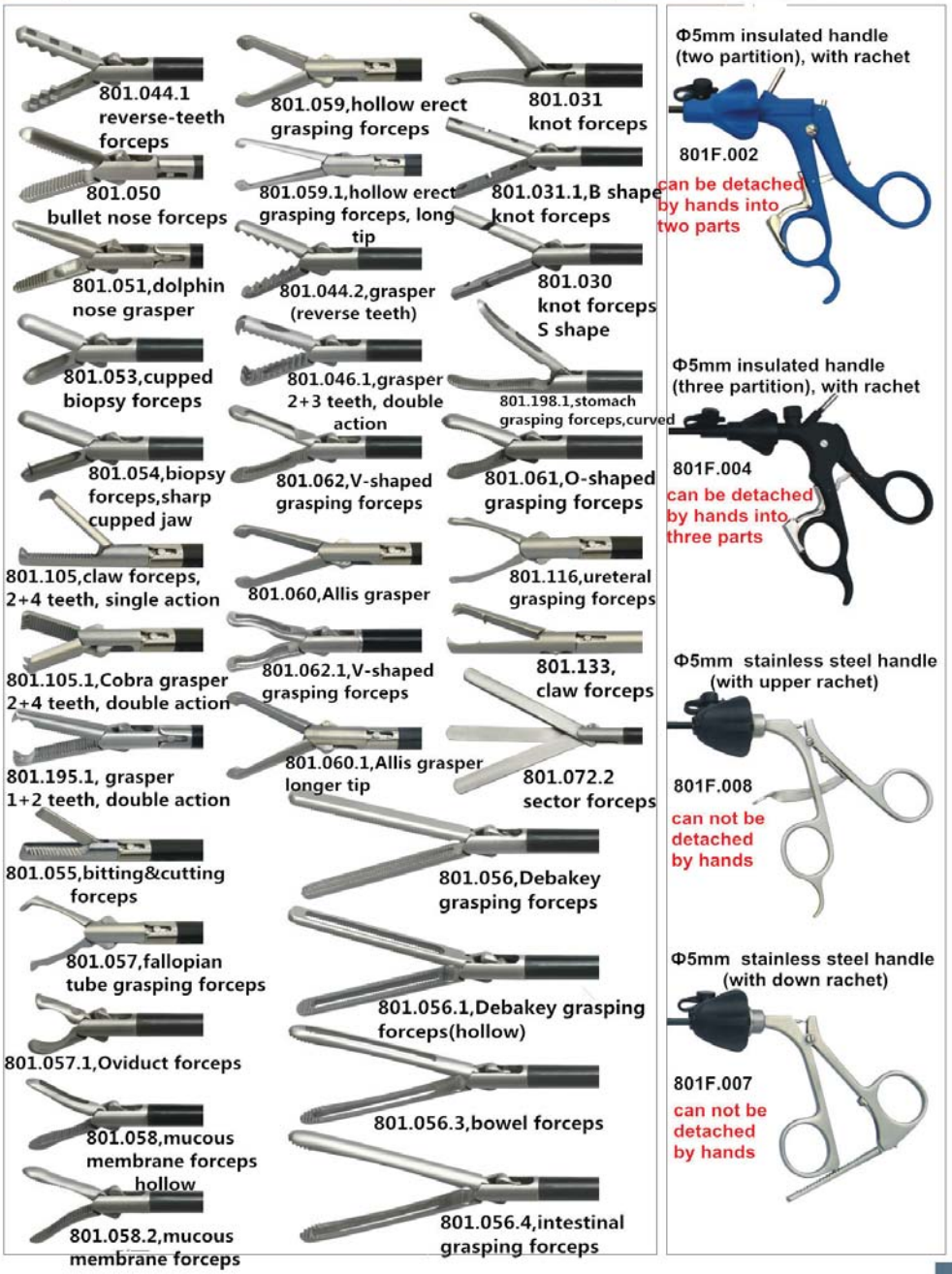
Laparoscopic Instruments

Forceps and Scissors,Φ5 X 330mm(common use,usually in stock)



Customize Length:
5mmx360mm/410mm/430mm/440mm/450mm/460mm

Forceps and Scissors,Φ5mmx330mm, common use,usually in stock



Customize Length:
5mmx360mm/410mm/430mm/440mm/450mm/460mm

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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

TÜV®

Legalization see reverse side

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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

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
   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° 1179274/2020
9. Stempel/Siegel, Stamp/seal
10. Unterschrift / Signature

S. Overkott

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

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:

tuv-sud.com/ps-cert

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

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

Legalization see reverse side

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ZLG-BS-244.10.08

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 Category(ies):

Class Is
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: 2020-04-03
Valid until: 2024-05-26

Date, 2020-04-03

Christoph Dicks
Head of Certification/Notified Body

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

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

Legalization see reverse side

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Bestätigt / Certified
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8. unter Nr. / under N° 1179273/2020
9. Stempel/Siegel, Stamp/seal
10. Unterschrift / Signature

S. Overkott

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60126740 0001

Report No.: 15056254 008

Manufacturer:
Zhejiang Geyi Medical
Instrument Co., Ltd.
The 5th Floor, NO.4 Building
No.190 Chutian Road
Xixing Street, Binjiang Zone
Hangzhou
310051 Zhejiang
China

Products:
Disposable Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60110361 0001

Expiry Date: 2022-12-13

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: 2018-03-21

Date: 2018-03-21

Notified Body

X. Ren

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60126740 0001
Report No.: 15056254 008

Manufacturer:
Zhejiang Geyi Medical
Instrument Co., Ltd.
The 5th Floor, NO.4 Building
No.190 Chutian Road
Xixing Street, Binjiang Zone
Hangzhou
310051 Zhejiang
China

Products:

- Disposable Cutting Surgical Staplers
- Disposable Surgical Staplers
- Disposable Hemorrhoidal Surgical Staplers
- Disposable Trocars
- Disposable Suction Irrigation Sets
- Disposable Endoscopic Retrieval Bags
- Disposable Curved Cutting Staplers
- Disposable Circumcision Staplers
- Disposable Veress Insufflation Needles

Date: 2018-03-21

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

X. Ren