

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

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Notified Body LGA P

X. Ren

ÜVRheinland

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

10/020 d 04 08 B TUV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg Doc. 1/1, Rev. 0

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

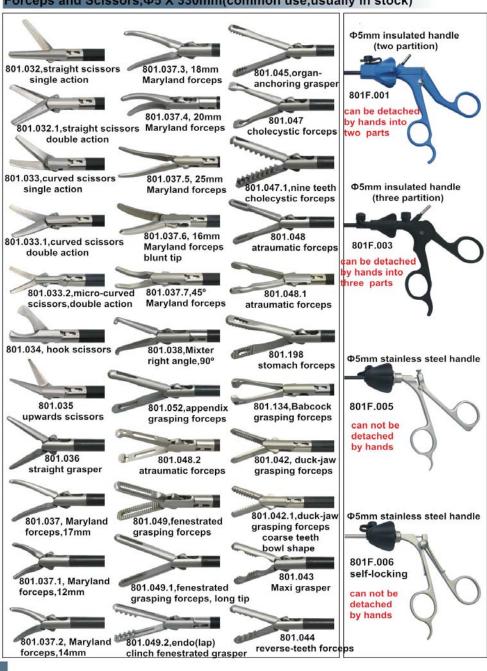
Date: 2018-03-21

TUV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval

Notified Bod ÜVRheinland

Laparoscopic Instruments

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



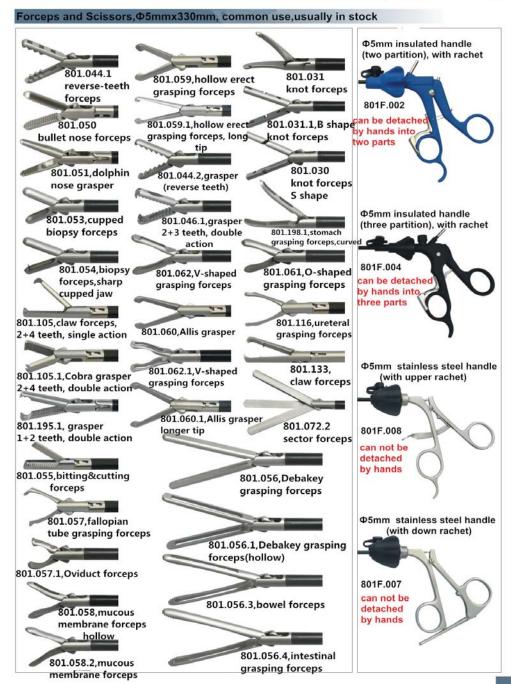
Page 9

Customize Length:

5mmx360mm/410mm/430mm/440mm/450mm/460mm

Laparoscopic Instruments





Page 10

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