

CE0197 and ISO13485 Certificates

EC Certificate

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

Registration No.: HD 60081169 0001

Report No.: 15056254 001

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:

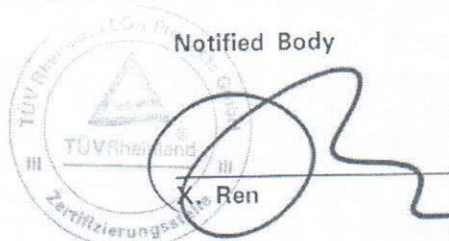
- Disposable Cutting Surgical Staplers
- Disposable Surgical Staplers
- Disposable Hemorrhoidal Surgical Staplers
- Disposable Trocars
- Disposable Suction Irrigation Sets

Expiry Date: 2017-12-13

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: 2012-12-14

Date: 2012-12-14



Notified Body

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.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Zhejiang Geyi Medical
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has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
Disposable Cutting Surgical Staplers, Disposable Surgical
Staplers, Disposable Hemorrhoidal Surgical Staplers,
Disposable Trocars, Disposable Suction Irrigation Sets**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60081170 0001

An audit was performed. Report No.: 15056254 001

This Certificate is valid until: 13.12.2017



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Certification Body



X. Ren

Date 14.12.2012

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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