

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



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.

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



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Zhejiang Geyi Medical
Instrument Co., Ltd.**
The 5th Floor, NO.4 Building
No.190 Chutian Road
Xixing Street, Binjiang Zone
Hangzhou
310051 Zhejiang
China

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
Disposable Medical Devices
(see attachment for products included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date: 2018-03-21
Certificate Registration No.: SX 60126742 0001
An audit was performed. Report No.: 15056254 008
This Certificate is valid until: 2020-12-13

Certification Body



Date 2018-03-21



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60126742 0001
Report No.: 15056254 008

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

Scope:

Products:

- Disposable Cutting Surgical Staplers
- Disposable Surgical Staplers
- Disposable Hemorrhoidal Surgical Staplers
- Disposable Trocars
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Certification Body



Date: 2018-03-21

