



TÜVRheinland®

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

Registration No.: HD 60113927 0001

Report No.: 15046198 007

Manufacturer: Changzhou Haida Medical
Equipment Co., Ltd.
Sanhekou Industrial Park
Zhenglu Town, Tianning District
Changzhou
213115 Jiangsu
China



Products: Medical Devices
(see attachment for products included)

Replaces Approval, Registration No.: HD 60105960 0001

Expiry Date: 2021-11-21

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: 2016-12-13

Date: 2016-12-13

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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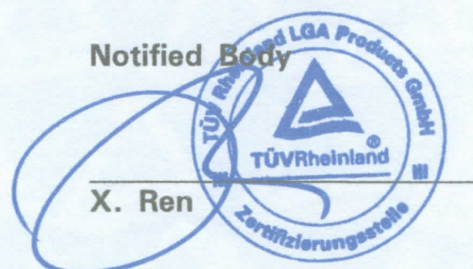
Products:

- Disposable Circular Staplers
- Disposable Linear Staplers
- Disposable Hemorrhoids Staplers
- Disposable Linear Cutter Staplers
- Disposable Purse String Staplers
- Disposable Curved Cutter Staplers
- Disposable Endo Cutter Staplers
- Disposable Skin Staplers
- Disposable Trocars
- Disposable Incision Retractors
- Single Incision Laparoscopy Surgery Ports
- Disposable Great Saphenous Vein Strippers
- Disposable Circumcision Staplers



Date: 2016-12-13

Notified Body



X. Ren