

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

Registration No.: HD 60122756 0001

Report No.: 15058264 007

Manufacturer: Ezisurg Medical Co., Ltd.
Rm. 103, Bldg. 2
No. 1690 Cailun Rd., China (Shanghai)
Pilot Free Trade Zone
201203 Shanghai
China

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60118703 0001

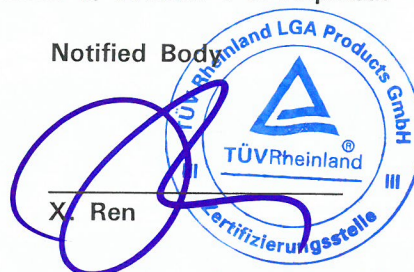
Expiry Date: 2018-11-07

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: 2017-12-04

Date: 2017-12-04

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 60122756 0001
Report No.: 15058264 007

Manufacturer: Ezisurg Medical Co., Ltd.
Rm. 103, Bldg. 2
No. 1690 Cailun Rd., China (Shanghai)
Pilot Free Trade Zone
201203 Shanghai
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Products:

- Linear Cutting Staplers and Loading Units for Single Use
- Circular Staplers for Single Use
- Ultrasonic Surgical Systems
- Linear Cutter Staplers and Loading Units for Single Use
- Loading Units of Linear Cutter Staplers for Single Use
- Linear Cutter Staplers for Single Use

Sites included:

1st Floor, Bldg. 10B, Rm. 506 and Rm. 504, Bldg. 6, 6th
Floor, Bldg. 6, No. 528 Ruiqing Rd., Zhangjiang Hi-Tech East
Park, 201201 Shanghai, China

Bldg. 1A, No. 199, Tianxiong Rd., Pudong New District,
201318 Shanghai, China

Date: 2017-12-04

