

EC Certificate

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

Registration No.: HD 60123618 0001

Report No.: 15051152 008

Manufacturer: Zhejiang Tiansong Medical

Instrument Co., Ltd.
No. 168, Jianduan Road
Tonglu Economic & Technical

Development Zone 311501 Hangzhou

China

Products: Medical Devices

(see attachment for products and additional site included)

Notified Box

X. Ren

TÜVRheinlan

Replaces Approval, Registration No.: HD 60087021 0001

Expiry Date: 2022-08-29

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: 2017-09-30

Date: 2017-09-30

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.



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

HD 60123618 0001

Report No.:

15051152 008

Manufacturer:

Zhejiang Tiansong Medical

Instrument Co., Ltd. No. 168, Jianduan Road Tonglu Economic & Technical

Development Zone 311501 Hangzhou

China

Products:

- Rigid Endoscopes
- Non-Sterile Reusable and Sterile Single-use Electrosurgical Electrodes
- Sterile Single-use Trocars
- Sterile Single-use Verres Needles
- Sterile Single-use Staplers with Staples
- Sterile Single-use Clip Appliers with Clips
- Non-absorbable Polymer Ligating Clips
- Medical Titanium Clips

Site included:

No. 588, Dongxing Road, Tonglu Economic Development Zone, Hangzhou 311501, P.R.China

Date: 2017-09-30

Notified Bodyna GA Products
TÜVRheinland

X. Ren