

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

Registration No.: HD 60079041 0001

Report No.: 15051152 001

Manufacturer: Hangzhou Tonglu Acme
Endoscope 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)

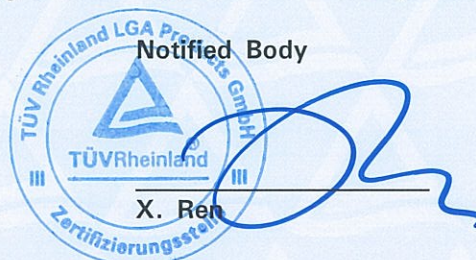
Replaces Approval, Registration No.: HD 60033551 0001

Expiry Date: 2017-08-29

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: 2012-10-29

Date: 2012-10-29



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**

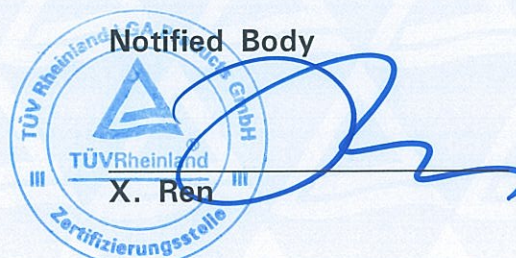
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Manufacturer: Hangzhou Tonglu Acme
Endoscope Co., Ltd.
No. 168, Jianduan Road
Tonglu Economic & Technical
Development Zone
311501 Hangzhou
China

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

Date: 2012-10-29



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

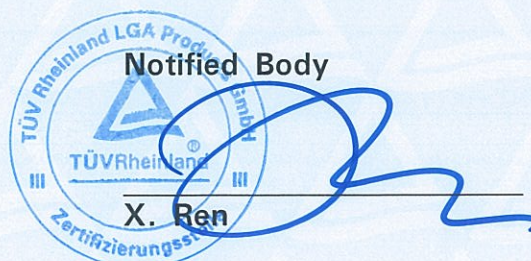
Registration No.: HD 60079041 0001
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Manufacturer: Hangzhou Tonglu Acme
Endoscope Co., Ltd.
No. 168, Jianduan Road
Tonglu Economic & Technical
Development Zone
311501 Hangzhou
China

Products:

- Non-absorbable Polymer Ligating Clips
- Medical Titanium Clips

Date: 2012-10-29



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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Manufacturer: Hangzhou Tonglu Acme
Endoscope Co., Ltd.
No. 168, Jianduan Road
Tonglu Economic & Technical
Development Zone
311501 Hangzhou
China

Site included:

No. 588, Dongxing Road, Tongjun Street, Tonglu,
Hangzhou 311501, P.R.China

Manufacture of 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 with Clips,
Non-absorbable Polymer Ligating Clips,
Medical Titanium Clips

Date: 2012-10-29



Notified Body

X. Ren