



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

Registration No.: HD 60122974 0001

Report No.: 15073963 004

Manufacturer: Changzhou Jihong
Medical Instrument Co., Ltd.
No. 256 Mingxin Middle Road
Wujin District
Changzhou
213164 Jiangsu
China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60096796 0001

Expiry Date: 2019-10-20

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: 2017-10-25

Date: 2017-10-25

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 60122974 0001
Report No.: 15073963 004

Manufacturer: Changzhou JiuHong
Medical Instrument Co., Ltd.
No. 256 Mingxin Middle Road
Wujin District
Changzhou
213164 Jiangsu
China

Products:

Disposable Endoscopic Hemoclips, Disposable Polyp Snares,
Disposable Electric Biopsy Forceps, Disposable Non-electric
Biopsy Forceps, Disposable Cytology Brushes,
Gastrointestinal and Biliary Balloon Catheters, Grasping
Forceps, Non-vascular Guidewires, Stone Extraction Balloons,
Stone Extraction Baskets, Kyphoplasty Balloon Catheters,
Multiple Band Ligators, Injection Needles, Balloon
Kyphoplasty Kits;

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

Disposable Bite Blocks, Cleaning Brushes for Endoscope,
Bougie Dilator Sets, Balloon Inflators, Biopsy Valves,
Polyp Traps

Site included:

No. 87, Majia Road, Lingjia Village, Hutang Town,
Wujin District, Changzhou, Jiangsu 213164, China

Date: 2017-10-25

Notified Body

X. Ren

