

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

Registration No.: HD 60146955 0001

Report No.: 17048277 013

Manufacturer: Chongqing Jinshan Science &
Technology (Group) Co., Ltd.
No. 18, Nishang Road
LiangLu Industrial City
401120 Yubei District, Chongqing
P.R. China

Products: Medical Devices

(see attachment for products included)

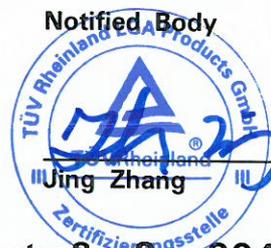
Replaces Approval, Registration No.: HD 60143591 0001

Expiry Date: 2024-05-26

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: 2020-02-18

Date: 2020-02-18



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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Report No.: 17048277 013

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Products:

- Capsule Endoscopy Systems
- PH Capsule Monitoring Systems
- Controllable Stomach Capsule Systems
- Impedance-pH Reflux Monitoring Systems
- Disposable Impedance-pH catheters
- Disposable pH catheters
- Video Gastroscope Systems
- Endoscopic Carbon Dioxide Regulation Units
- Hysteroscopy Systems
- Disposable Hysteroscopic systems
- Argon-enhanced electrosurgical systems
(Argon-enhanced electrosurgical system generator,
Argon-enhanced open-surgery electrosurgical handpiece/
electrode, Argon-enhanced endoscopic electrosurgical
electrode)
- Endoscopic Irrigation Pumps

Date: 2020-02-18

