

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

Registration No.: HD 60127938 0001

Report No.: 16801992 009

Manufacturer: Shangxian Minimal Invasive
Inc.
1st Floor,Block B2-2
China medicine innovation park
Mulan road,Hi-tech development zone
Benxi
117004 Liaoning
China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60114910 0001

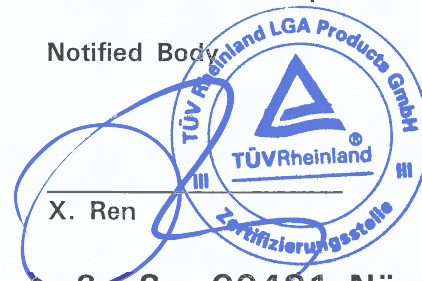
Expiry Date: 2023-07-27

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: 2018-07-28

Date: 2018-06-26

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**

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Report No.: 16801992 009

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Products:

- Disposable Biopsy Forceps
- Disposable Endoscopic Distal Attachments
- Disposable Hemostasis Clips and Delivery Systems
- Capsule Endoscopy Systems
- Disposable Hemostasis Clips
- Disposable Grasping Forceps
- Disposable Injection Needles
- Disposable Polypectomy Snares

Aspects of manufacture concerned securing and
maintaining sterile conditions:

- Disposable Guide Wires

Site included:

501, IT Int'l Building, No. 3 West Yuanhang Road,
Hunnan New District, Shenyang, 110179 Liaoning, China

Date: 2018-06-26

Notified Body

