

## **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)

Notified Bod

TÜVRheinlan

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

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

Doc. 1/1, Rev. 0

Attachment to Certificate

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:

- 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

