

EC Certificate



Full Quality Assurance System Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2114740-1

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

Aspects of Manufacture concerned Securing and Maintaining Sterile
Conditions of Disposable Guide Wires

Replaces Approval, Registration No.: HD 60148689 0001

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.

Report No.: 190130980 170

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-24



Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2114740-1

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

The scope of certification includes the following sites:

No.	Location	Product groups
/01	Shangxian Minimal Invasive Inc. 1001, IT Int'l Building, No.3 West Yuanhang Road, Hunnan New District, Shenyang, 110179 Liaoning, P.R. China	Same as the above mentioned products
/02	Shangxian Minimal Invasive Inc. No.1, Floor 1, Building 1, West Binhe Road, Benxi Economic Development Zone, Liaoning, P.R. China	Same as the above mentioned products

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Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2114740-1

Organization: Shangxian Minimal Invasive Inc.
1st Floor, Block B2-2, China Medicine Innovation Park, Mulan Road,
Hi-tech Development Zone, Benxi, 117004 Liaoning,
P.R. China

Scope: Design and Development, Manufacture and Distribution of 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 Guide Wires, Disposable Polypectomy Snares and Medical Protective Masks

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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