

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


TÜVRheinland

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.

Report No.: 190130980 110
Effective date: 2021-11-22
Expiry date: 2024-04-06
Issue date: 2021-11-22



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

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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o 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	Manufacture 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
/02	c/o Shangxian Minimal Invasive Inc. 1001, IT Int'l Building, No.3 West Yuanhang Road, Hunnan New District, Shenyang 110179, Liaoning, P.R. China	Design and Development 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

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The scope of certification also covers the following:

- | | | |
|-----|--|---|
| /03 | c/o Shangxian Minimal Invasive Inc.
No.1, Floor 1,
Building 1, West Binhe Road,
Benxi Economic Development Zone,
117002, Liaoning,
P.R. China | ETO sterilization 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 |
| /04 | c/o Shangxian Minimal Invasive Inc.
No.2, Building 4, No.18 Shennong Street,
Economic and Technological
Development Zone,
Benxi
117004, Liaoning,
P.R. China | Manufacture of Medical Protective Masks |

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