

# Hemostasis

## Delivery

### Pre-load hemoclip)



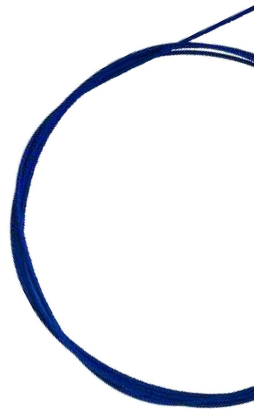
## Intended use

Clamping the mucosa tissue of alimentary cavity under the guide of endosc

### A) Hemostasis for

- 1) Mucosal / sub-mucosal defects <3cm
- 2) Bleeding ulcers
- 3) Arteries <2mm
- 4) Surgery sites
- 5) Diverticula in colon

### B) Closure of GI luminal perforations



## Features

The clip is pre-load in disposable delivery system, which is convenient to use

- Accurate sync-rotation offers exact clip deployment.
- Reinforced design makes the clip performance more steady.
- The biggest opening is 13mm after maximize the clip.
- Single time opening.

## Specifications

Model	Working length	Jaw angle
SX-HC-1650-090L	1650mm	90°
SX-HC-1650-135L	1650mm	135°
SX-HC-2300-090L	2300mm	90°
SX-HC-2300-135L	2300mm	135°

# Grasping Forceps (with basket)



## Intended use

Removal of foreign bodies in upper and lower digestive tract .

## Features

- Good rotation performance and hand control feeling.
- Special alloyed material makes good shape retention.

## Specifications

Model	Dia.(mm)	Working channel(mm)	Working L
MI-FG-ZJ-18*800-20	1.8	≥2.0	800
MI-FG-ZJ-18*800-30	1.8	≥2.0	800
MI-FG-ZJ-18*800-40	1.8	≥2.0	800
MI-FG-ZJ-18*1200-20	1.8	≥2.0	1200
MI-FG-ZJ-18*1200-30	1.8	≥2.0	1200
MI-FG-ZJ-18*1200-40	1.8	≥2.0	1200
MI-FG-ZJ-18*1600-20	1.8	≥2.0	1600
MI-FG-ZJ-18*1600-30	1.8	≥2.0	1600
MI-FG-ZJ-18*1600-40	1.8	≥2.0	1600
MI-FG-ZJ-23*1600-20	2.3	≥2.8	1600
MI-FG-ZJ-23*1600-30	2.3	≥2.8	1600
MI-FG-ZJ-23*1600-40	2.3	≥2.8	1600
MI-FG-ZJ-23*1800-20	2.3	≥2.8	1800
MI-FG-ZJ-23*1800-30	2.3	≥2.8	1800
MI-FG-ZJ-23*1800-40	2.3	≥2.8	1800



# 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



# 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

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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# 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

The scope of certification also covers the following:

- |     |  |   |
|-----|--|---|
| /03 | c/o Shangxian Minimal Invasive Inc.<br>No.1, Floor 1,<br>Building 1, West Binhe Road,<br>Benxi Economic Development Zone,<br>117002, Liaoning,<br>P.R. China                   | ETO sterilization of Disposable Biopsy<br>Forceps, Disposable Endoscopic Distal<br>Attachments, Disposable Hemostasis Clips<br>and Delivery Systems, Capsule Endoscopy<br>Systems, Disposable Hemostasis Clips,<br>Disposable Grasping Forceps, Disposable<br>Injection Needles, Disposable Guide Wires,<br>Disposable Polypectomy Snares |
| /04 | c/o Shangxian Minimal Invasive Inc.<br>No.2, Building 4, No.18 Shennong Street,<br>Economic and Technological<br>Development Zone,<br>Benxi<br>117004, Liaoning,<br>P.R. China | Manufacture of Medical Protective Masks   |

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# 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



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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

Report No.: 190130980 170

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-24



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