Disposable Hemostasis Clips and Delivery Systems

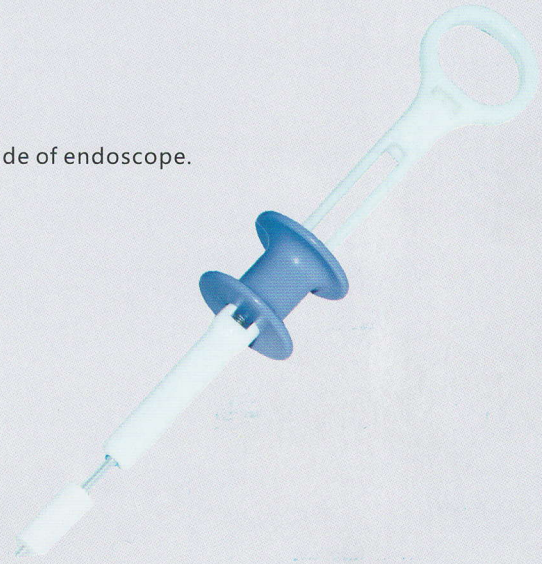
Intended use

Clamping the mucosa tissue of alimentary cavity under the guide of endoscope.

A) Hemostasis for

1) Mucosal / sub-mucosal defeats <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.

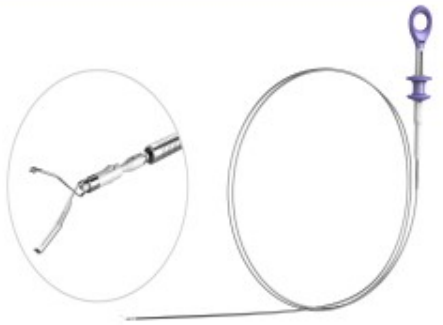
· Accurate sync-rotation offers exact clip deployment.

· Reinforced design makes the clip performance more steady.

· The biggest opening is 14mm after maximize the clip.

Specifications

Model	Working length	Jaw angle	Working Channel
SX-HC-1650-090L	1650mm	90°	≥2.8mm
SX-HC-1650-135L	1650mm	135°	≥2.8mm
SX-HC-2300-090L	2300mm	90°	≥2.8mm
SX-HC-2300-135L	2300mm	135°	≥2.8mm

Single-Use Hemoclips and Delivery System （**Max-Clip**）					Picture
Model	Working length	Jaw angle	Arm length	Openning	
SX-HC-1650-90L	1650mm	90°	5.0mm	14.5mm (max)	
SX-HC-1650-135L	1650mm	135°	5.7mm	14.5mm (max)	
SX-HC-2300-90L	2300mm	90°	5.0mm	14.5mm (max)	
SX-HC-2300-135L	2300mm	135°	5.7mm	14.5mm (max)	

EC Certificate

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

TÜVRheinland®

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.

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

X. Ren

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

X. Ren

Date: 2018-06-26

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

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

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Disposable endoscopic distal attachments
Model: XT- DL - 092-40 、XT-DL- 098 - 40 、XT-DL-099 - 40 、XT-DL - 105 - 40 、XT-DL - 108 - 40 、XT-DL-115 - 40 、X T-DL-118-40 、XT-DL -1 22 - 40 、XT-DL - 128 - 40 、XT-DL- 132-40 、XT-DL- 148- 40 XT-DL-132AB XT-DL-115A

der Klasse: /
of class: /
de la classe: /
di classe:

IIa

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d’évaluation de la conformité: /
Procedura di valutazione della conformità:

Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4
Directive 93/42/EEC Annex II, excluding Section 4
Directive 93/42/CEE Annexe II, hors section 4
Direttiva 93/42/CEE senza Allegato II, sezione 4

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

HD 60127938 0001

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Benxi. 3rd. July. 2018
Ort, Datum / Place, date /
Lieu, date / Luogo, data

For and on behalf of
沈阳尚贤医疗系统有限公司
SHANGXIAN MINIMAL INVASIVE INC.

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

(CEO)

Authorised signature(s)

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

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

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Reusable delivery systems for disposable hemostasis clips
Model: SX-H-1650 SX-H-1950 SX-H-2300

der Klasse: /
of class: /
de la classe: /
di classe:

Class I

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d’évaluation de la conformité: /
Procedura di valutazione della conformità:

Medical Devices Directive 93/42/EEC Annex VII

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

16806618.001

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland (China) Ltd.

Benxi. 2017-2-21

Ort, Datum / Place, date /
Lieu, date / Luogo, data

For and on behalf of
沈阳尚贤微创医疗器械股份有限公司
SHANGXIAN MINIMAL INVASIVE INC.

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

Authorized signature(s)

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

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

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Disposable Hemostasis Clips and Delivery Systems

der Klasse: /
of class: /
de la classe: /
di classe:

IIa

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4
Directive 93/42/EEC Annex II, excluding Section 4
Directive 93/42/CEE Annexe II, hors section 4
Direttiva 93/42/CEE senza Allegato II, sezione 4

Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

HD 60127938 0001

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

For and on behalf of
沈阳尚贤医疗系统有限公司
SHANGXIAN MINIMAL INVASIVE INC.

SX-HC-1650-90，SX-HC-1650-90L，SX-HC-1650-135，SX-HC-1650-135L，SX-HC-2300-90，SX-HC-2300-90L，SX-HC-2300-135，SX-HC-2300-135L；SX-C-90，SX-C-135，SX-HR-1650-1，SX-HR-1650-2，SX-HR-2300-1，SX-HR-2300-2

Benxi, 12th July, 2018
Ort, Datum / Place, date /
Lieu, date / Luogo, data

Wang Yan Zhe (Vice-president)
Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

Authorized signature(s)

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-06-26
Certificate Registration No.:	SX 60127939 0001
An audit was performed. Report No.:	16801992 009
This Certificate is valid until:	2021-04-06

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-06-26

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60127939 0001
Report No.: 16801992 009

Organization:

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

Scope:

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 Guide Wires
- Disposable Polypectomy Snares

Site included:

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

Design and Development, Distribution of the a.m. products

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

X. Ren

Date: 2018-06-26

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

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

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Disposable hemostasis clips
Model: SX-C-90 SX-C-135

der Klasse: /
of class: /
de la classe: /
di classe:

IIa

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d’évaluation de la conformité: /
Procedura di valutazione della conformità:

Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4
Directive 93/42/EEC Annex II, excluding Section 4
Directive 93/42/CEE Annexe II, hors section 4
Direttiva 93/42/CEE senza Allegato II, sezione 4

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

HD 60114910 0001

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg

Benxi, 2017-2-21

Ort, Datum / Place, date /
Lieu, date / Luogo, data

For and on behalf of
沈阳尚贤微创医疗器械股份有限公司
SHANGXIAN MINIMAL INVASIVE INC.

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

Authorized signature(s)

TÜVRheinland®

CE Technical Documentation Review Report

Applicant:	**Shangxian Minimal Invasive Inc.** 1st Floor, Block B2-2, China medicine innovation park, Mulan road, Hi-tech development zone, 117004 Benxi, Liaoning, China
Report Number:	**16806618.001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII
Product(s):	**Reusable Delivery Systems for Disposable Hemostasis Clips**
Type(s)/Model(s):	SX-H-1650，SX-H-1950，SX-H-2300
Classification:	Class I (according to manufacturer's declaration)
Examination period:	Jan.03.2017
Date of expiry:	Jan.02.2022
Review result:	During the examination of the provided Technical Documentation (No.: SYSX-CE-114-001, Revision: A/0, dated 2016-07-02), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd.

Product Safety • Quality Assurance Rheinland

Yuhong CHEN
Manager
Medical Services

Rev.01, 2002-10-10

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China
Tel：(8610)6566 6660 Fax: (8610)6566 6667
e-mail: info@bj.chn.tuv.com Internet: http://www.chn.tuv.com