MULTIBAND LIGATION-SYSTEM

EASY, RELIABLE, LATEX FREE

The MICRO-TECH multiband ligating system is suitable for the effective treatment of bleedings in esophageal varices and anorectal hemorrhoids. The complete system is preloaded for 4 or 6 ligations and can be easily installed.

The silicone cap provides a clear view and a reliable suction of tissue. It is the only system also available in a latex-free variant, which significantly reduces the risk of an allergic reaction in sensitive patients.

SPECIFIC CHARACTERISTICS

- Easy assembly and handling
- Suitable for endoscopes of 9.4 to 14.0 mm in diameter
- For minimum working channels of 2.8 mm diameter
- With flush attachment
- Preloaded for 4/6 ligations
- Ligation-design with or without latex

Silicone cap with release thread

Latex cap with release thread

SPECIFICATIONS

REF	Soft cap Ø mm	Endoscope Ø mm	X-shooter	Thread length mm	Thread color
LATEX					
MBLS-6F	8.8	9.4 – 13.0	6	1450	Blue/transparent
MBLS-4F	8.8	9.4 – 13.0	4	1450	Blue/transparent
MBLS-XL-6F	9.8	11.0 – 14.0	6	1900	Blue/transparent
MBLS-XL-4F	9.8	11.0 – 14.0	4	1900	Blue/transparent
LATEX FREE					
MBLS-6F-NL	8.8	9.4 – 13.0	6	1450	Yellow/black
MBLS-4F-NL	8.8	9.4 – 13.0	4	1450	Yellow/black
MBLS-XL-6F-NL	9.8	11.0 – 14.0	6	1900	Yellow/black
MBLS-XL-4F-NL	9.8	11.0 – 14.0	4	1900	Yellow/black

Packaging unit: 1 piece, relay prices on request

Product Service

CERTIFICATE

No. Q5 18 01 48850 038

Holder of Certificate: **Micro-Tech (Nanjing) Co., Ltd.**
NO.10 Gaoke Third Road
Nanjing National Hi-Tech Industrial Development Zone
210032 Nanjing, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Ovum Pick-up Needle
Design and Development, Production and Distribution of Single-Use Biopsy Forceps, Grasping Forceps, Multiple Band Ligator Set, Retrieve Net, Endoscopic Ultrasound Aspiration Needle, Single Use Electrosurgical Knife, Disposable Balloon Inflation Device**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1821723

Valid from: 2018-06-01
Valid until: 2021-05-31

0405276870720B

Date, 2018-04-30

Stefan Preiß

Page 1 of 2

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Product Service

CERTIFICATE
No. Q5 18 01 48850 038

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Micro-Tech (Nanjing) Co., Ltd.
NO.10 Gaoke Third Road, Nanjing National Hi-Tech Industrial Development Zone, 210032 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Micro-Tech (Nanjing) Co., Ltd.
No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech Industrial Development Zone, 210032 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

EC Certificate Full Quality Assurance System: CN13/20558

The management system of

Micro-Tech (Nanjing) Co., Ltd.

No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone,
Nanjing 210032, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

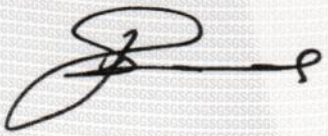
The scope of registration appears on page 2 of this certificate.

This certificate is valid from 5 January 2017 until 9 September 2021
And remains valid subject to satisfactory surveillance audits.
Re certification audit due before 4 September 2019
Issue 10. Certified since 26 September 2013

Certification is based on reports numbered CN/SZH 8403MDD

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by



SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 02 0315 M2

Micro-Tech (Nanjing) Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 10

Detailed scope

Sterile Non-Vascular Stent (Biliary Stent, Esophageal Stent, Intestinal Stent, Tracheal Stent and Prostatic Stent), Sterile Medical devices used for clinical endoscopic procedure including Dilation Balloon (Disposable Dilation Balloon, Disposable Multistage Dilation Balloon Catheter), Disposable Hot Biopsy Forceps, Injection Needle, Nasal Biliary Drainage Set, Snare, Stone Extraction Basket, Cold Snare, Hydro Slide Guidewire, Biliary Drainage Catheter, Biliary Drainage Catheter Introducer System, Biliary Drainage Catheter with Introducer System, Biliary Stone Retrieval Balloon Catheter, Repositionable Hemostasis Clipping Device, Pancreatic Pseudocyst Stent with Delivery System, Sphincterotome, Non-sterile OXY CO_2 Bite Block.
Annex II (Sterility aspects only-Restricted to the aspects of manufacture concerned with securing and maintaining sterile condition): Sterile Spray Catheter, Sterile Cytology Brush, Sterile Fixed Wire Balloon (ABC Dilatation Balloon Catheter, Rapide™ Multistage Dilatation Balloon Catheter)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, P.R. China