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.

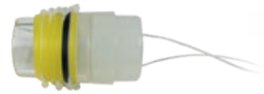
SPECIFICATIONS

REF	Soft cap Ø mm	Endoscope Ø mm	X-shooter	Thread length mm	Thread color
LATEX					
MBLS-6F	8.8	9.2 – 13.0	6	1450	Blue/transparent
MBLS-4F	8.8	9.2 – 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	9.2 – 13.0	6	1450	Yellow/black
MBLS-4F-NL	8.8	9.2 – 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

SPECIFIC CHARACTERISTICS

- Easy assembly and handling
- Suitable for endoscopes of 9.2 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

Declaration of Conformity

Manufacturer Micro-Tech (Nanjing) Co., Ltd.
Address NO. 10 Gaoke Third Road,
Nanjing National Hi-tech, Industrial Development Zone,
Nanjing 210032, Jiangsu Province, People's Republic of China

European Representative Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product name Multiple Band Ligator Set

REF Number See Attachment 1

UMDNS Code 12332

Classification: Ⅱa (According to MDD annexⅨ, Rule 5)

Conformity Assessment Route: Annex II (without II.4) of MDD 93/42/EEC

We herewith declare that the above-mentioned products meet the transposition into national law, the provisions of the following EC Council Directives. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable Directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body: TUV SUD Product Service GmbH, Ridlerstr. 65, 80339 Munchen, Germany

Identification number: 0123

Certificate Number: G1 048850 0047

Expire date of the certificate: 2028-12-31

Start of CE Marking: 2016-08-12

Signature: Frank Liu **Date:** 2023-07-20

Title: Management Representative

The reference standards:

- EN ISO 13485:2016/A11:2021 Medical devices – Quality management systems- Requirements for regulatory purposes
- EN ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- EN ISO 20417:2021 Information supplied by the manufacturer with medical devices
- EN ISO 14971:2019 Medical devices - Application of risk management to medical devices
- ISO/TR 24971-2020 Medical devices — Guidance on the application of ISO 14971
- EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing
- EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- EN ISO 10993-7:2008/AC: 2009 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residual
- EN ISO 10993-10:2013 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- EN ISO 10993-11:2018 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
- ASTM F1980-16 Standard guide for accelerated aging of sterile barrier systems for medical devices
- EN ISO 8536-4: 2020 Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)
- ISO/TR 20416 Medical devices — post-market surveillance for manufacturers
- IMDRF MDCE WG/N56 FINAL: 2019 Clinical Evaluation
- EN ISO 11135:2014+A1:2019 Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
- EN ISO 11737-1:2018+A1:2021 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products Sterilization of medical devices
- EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1:

Classification of air cleanliness

- EN 17141:2020 Cleanrooms and associated controlled environments — Biocontamination control
- ISO 8600-1-2015 Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements
- EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices
- MEDDEV 2.7.1 (Rev. 4) Clinical evaluation: a guide for manufacturers and notified bodies
- MEDDEV 2.12.1 (Rev. 8) Guidelines on a medical devices vigilance system
- MDCG 2018-1 Guidance on basic UDI-DI and changes to UDI-DI
- MDCG-2019-1MDCG guiding principles for issuing entities rules on basic UDI-DI
- MDCG-2019-7Guidance on Article 15 MDR-IVDR Person responsible for Regulatory Compliance
- MDCG 2020-5 Guidance on Clinical Evaluation
- MDCG 2020-6 Guidance on Sufficient Clinical Evaluation

Attachment 1

CE MBLS Product List

Item	REF	Endoscope OD φ(mm)	Band Quantity (pcs)	Pull Catheter Diameter φ(mm)	Pull Thread Length (cm)	Minimum Working Channel φ(mm)	Band Type
1	MBLS-7F-NL	9.4~13.0	7	2.0±0.5	145±30	2.8	Non-Latex
2	MBLS-6F-NL	9.4~13.0	6	2.0±0.5	145±30	2.8	Non-Latex
3	MBLS-4F-NL	9.4~13.0	4	2.0±0.5	145±30	2.8	Non-Latex
4	MBLS-3F-NL	9.4~13.0	3	2.0±0.5	145±30	2.8	Non-Latex
5	MBLS-XS-7F-NL	8.6~9.2	7	2.0±0.5	145±30	2.8	Non-Latex
6	MBLS-XS-6F-NL	8.6~9.2	6	2.0±0.5	145±30	2.8	Non-Latex
7	MBLS-XS-4F-NL	8.6~9.2	4	2.0±0.5	145±30	2.8	Non-Latex
8	MBLS-XS-3F-NL	8.6~9.2	3	2.0±0.5	145±30	2.8	Non-Latex
9	MBLS- XL-7F-NL	11~14.0	7	2.0±0.5	190±30	2.8	Non-Latex
10	MBLS- XL-6F-NL	11~14.0	6	2.0±0.5	190±30	2.8	Non-Latex
11	MBLS-XL-4F-NL	11~14.0	4	2.0±0.5	190±30	2.8	Non-Latex
12	MBLS-XL-3F-NL	11~14.0	3	2.0±0.5	190±30	2.8	Non-Latex
13	MBLS-P-6F-NL	8.5	6	2.0±0.5	145±30	2.8	Non-Latex
14	MBLS-7F	9.4~13.0	7	2.0±0.5	145±30	2.8	Latex
15	MBLS-6F	9.4~13.0	6	2.0±0.5	145±30	2.8	Latex
16	MBLS-4F	9.4~13.0	4	2.0±0.5	145±30	2.8	Latex
17	MBLS-3F	9.4~13.0	3	2.0±0.5	145±30	2.8	Latex
18	MBLS-XS-7F	8.6~9.2	7	2.0±0.5	145±30	2.8	Latex
19	MBLS-XS-6F	8.6~9.2	6	2.0±0.5	145±30	2.8	Latex
20	MBLS-XS-4F	8.6~9.2	4	2.0±0.5	145±30	2.8	Latex
21	MBLS-XS-3F	8.6~9.2	3	2.0±0.5	145±30	2.8	Latex
22	MBLS- XL-7F	11~14.0	7	2.0±0.5	190±30	2.8	Latex
23	MBLS- XL-6F	11~14.0	6	2.0±0.5	190±30	2.8	Latex
24	MBLS-XL-4F	11~14.0	4	2.0±0.5	190±30	2.8	Latex
25	MBLS-XL-3F	11~14.0	3	2.0±0.5	190±30	2.8	Latex
26	MBLS-P-6F	8.5	6	2.0±0.5	145±30	2.8	Latex

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 048850 0047 Rev. 01

Manufacturer:

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

Product Category(ies):

Single-Use Biopsy Forceps,
Multiple Band Ligator Set,
Endoscopic Ultrasound Aspiration Needle,
Single Use Electrosurgical Knife,
Extraction Basket / short-wire compatible,
Biliary Drainage Catheter Set / short-wire compatible,
Sphincterotome / short-wire compatible,
Retrieval Balloon / short-wire compatible,
Single-Use Coagulation Forceps

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1921726

Valid from: 2019-11-15
Valid until: 2023-08-18

Date, 2019-11-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 048850 0047 Rev. 01

Facility(ies):

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

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

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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