



DILATION BALLOONS

SIMPLY EXPAND RELIABLY AND EFFECTIVELY

The dilation balloons from MICRO-TECH stand for maximum quality. MICRO-TECH produces all the dilation balloons itself – using state-of-the-art European and American production technology. Two x-ray markings indicate the exact working length of the balloon, thereby ensuring its precise positioning. Under application of pressure, the

balloon is rapidly filled to acquire its predefined expansion width. Furthermore, the high-pressure design ensures the balloon retains its shape over the entire working length, thereby allowing optimum dilation success. All balloons are available as TTS (through-the-scope) systems up to a diameter of 18 mm and a catheter length of 1800 mm.

SPECIFIC CHARACTERISTICS

- Dimensionally stable high pressure design
- 2 X-ray markers on opposite ends to indicate the exact working length of the balloon
- Separate guide wire and insufflation lumens
- Conical shaped catheter tip
- Rapid expansion
- Constant dilation over the entire length
- Guide-wire compatible up to 0.035 inches



X-ray marking



Conical tip

SUCCESSFUL IN PRACTICAL USE

Stenoses are effectively dilated using the MICRO-TECH dilation balloons. The balloon dilates the stenosis safely and gently and prepares the area to be treated in an optimum manner. The uniform distribution of pressure over the entire working length of the balloon and the outstanding dimensional stability during dilation guarantee excellent therapeutic success over the entire length of the stenosis.



Endoscopic control during dilation therapy

SPECIFICATIONS

REF	Balloon Ø mm	Balloon length mm	Catheter Ø fr.	Catheter length mm	Channel Ø mm	Application
TTS - DILATION BALLOONS						
BDC-8/55-7/18	8	55	7	1800	2.8	Oesophagus/Bile duct
BDC-8/55-7/24	8	55	7	2400	2.8	Pylorus/Colon
BDC-10/55-7/18	10	55	7	1800	2.8	Oesophagus/Bile duct
BDC-10/55-7/24	10	55	7	2400	2.8	Pylorus/Colon
BDC-12/55-7/18	12	55	7	1800	2.8	Oesophagus
BDC-12/55-7/24	12	55	7	2400	2.8	Pylorus/Colon
BDC-16/55-7/18	16	55	7	1800	2.8	Oesophagus
BDC-16/55-7/24	16	55	7	2400	2.8	Pylorus/Colon
BDC-18/55-7/18	18	55	7	1800	2.8	Oesophagus
BDC-18/55-7/24	18	55	7	2400	2.8	Pylorus/Colon
BDC-20/55-7/18	20	55	7	1800	4.2	Oesophagus
BDC-20/55-7/24	20	55	7	2400	4.2	Pylorus/Colon
BDC-12/80-7/18	12	80	7	1800	2.8	Oesophagus
BDC-12/80-7/24	12	80	7	2400	2.8	Pylorus/Colon
BDC-16/80-7/18	16	80	7	1800	2.8	Oesophagus
BDC-16/80-7/24	16	80	7	2400	2.8	Pylorus/Colon
BDC-18/80-7/18	18	80	7	1800	2.8	Oesophagus
BDC-18/80-7/24	18	80	7	2400	2.8	Pylorus/Colon
BDC-20/80-7/18	20	80	7	1800	4.2	Oesophagus
BDC-20/80-7/24	20	80	7	2400	4.2	Pylorus/Colon
ACHALASIE-BALLOONS						
BDC-26/80-7/10	26	80	7	1000	–	Achalasia
BDC-30/80-7/10	30	80	7	1000	–	Achalasia
BDC-34/80-7/10	34	80	7	1000	–	Achalasia
FIXED WIRE BALLOONS						
FWB-06/80-6/18-M	6-7-8	80	6	1800	2.8	Upper/lower GI
FWB-08/80-6/18-M	8-9-10	80	6	1800	2.8	Upper/lower GI
FWB-10/80-6/18-M	10-11-12	80	6	1800	2.8	Upper/lower GI
FWB-12/80-6/18-M	12-13.5-15	80	6	1800	2.8	Upper/lower GI
FWB-15/80-6/18-M	15-16.5-18	80	6	1800	2.8	Upper/lower GI
FWB-18/80-6/18-M	18-19-20	80	6	1800	2.8	Upper/lower GI

Packaging unit: 1 piece / suitable for guide wires with 0.035"



GOLDKNIFE

ONE INSTRUMENT, FOUR OPERATION STEPS

The GOLDKNIFE from MICRO-TECH allows for effective and reliable endoscopic submucosal dissections. Thanks to the combination of water-jet and electro-surgery, all working steps - marking, injection, dissection and coagulation - can be performed without switching instruments. The high-pressure water jet function creates a submuco-

sal pillow of water that allows replenishment at any time to protect against thermal and mechanical injuries. The handle facilitates a smooth and seamless extension of the knife. The balanced rigidity of the tube also enables precise knife guidance. Choose from three different needle tips with different cutting and coagulation properties.

SPECIFIC CHARACTERISTICS

- Water-jet and electro-surgery in one
- Independent marking, injection, dissection and coagulation without switching instruments
- Replenishing the water pillow (optional) while dissecting and resecting
- 3 different knife types



Handle with rotatable coagulation connection



Type I: Great freedom of movement, versatile, higher level of difficulty



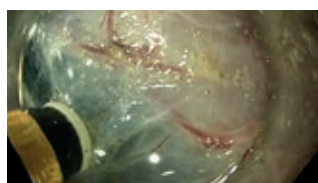
Type T: Ideal for removing under tension. Better coagulation options and optimized cutting direction while dissecting



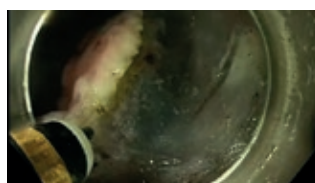
Type O: The safety model with a spherical, insulated tip



Marking



Injection water cushion



Dissection



Findings after removal

SPECIFICATIONS

REF	Shape of the knife tip	Length of the knife tip mm	Working length mm	Working channel Ø mm
GOLDKNIFE				
MK-I-1-165	I	1.5	1650	2.8
MK-I-1-235	I	1.5	2350	2.8
MK-I-2-165	I	2	1650	2.8
MK-I-2-235	I	2	2350	2.8
MK-I-4-165	I	4	1650	2.8
MK-I-4-235	I	4	2350	2.8
MK-T-1-165	T	1.5	1650	2.8
MK-T-1-235	T	1.5	2350	2.8
MK-T-2-165	T	2	1650	2.8
MK-T-2-235	T	2	2350	2.8
MK-T-4-165	T	4	1650	2.8
MK-T-4-235	T	4	2350	2.8
MK-O-1-165	O	1.5	1650	2.8
MK-O-1-235	O	1.5	2350	2.8
MK-O-2-165	O	2	1650	2.8
MK-O-2-235	O	2	2350	2.8
MK-O-4-165	O	4	1650	2.8
MK-O-4-235	O	4	2350	2.8

Packaging unit: 1 piece

EC Certificate Full Quality Assurance System: Certificate CN19/41071

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 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 26 September 2013
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CN/SZH 8403MDD

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

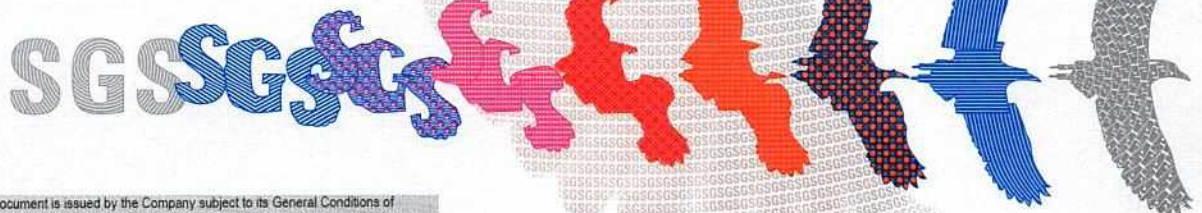
Authorised by

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4, EN rev. 02

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Micro-Tech (Nanjing) Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 1

Detailed scope

Sterile Non Vascular Stent (Biliary Stent, Esophageal Stent, Intestinal Stent, Tracheal Stent)
Sterile medical devices used for clinical endoscopic procedure including Sterile Dilation Balloon (Disposable Dilation Balloon , Disposable Multistage Dilation Balloon Catheter), Sterile Disposable Hot Biopsy Forceps, Sterile Injection Needle, Sterile Nasal Biliary Drainage Set, Sterile Hot Snare Sterile Stone Extraction Basket, Sterile Cold Snare, Non Vascular sterile Hydro Slide Guidewire, Sterile Biliary Drainage Catheter, Biliary Drainage Catheter Introducer System, Biliary Drainage Catheter with Introducer System, Sterile Biliary Stone Retrieval Balloon Catheter, Sterile Repositionable Hemostasis Clipping Device to be intended for short term use Sterile Pancreatic Pseudocyst Stent with Delivery System to be intended for short term use in the body within 30 days, Sterile Sphincterotome, Non sterile OXY CO₂ Bite Block used to protect the endoscope insertion tube and oesophageal dilators from being bitten by the patient. Sterile Biliary Nitinol Stent Set, short-wire compatible
Class I (Sterility aspects only Restricted to the aspects of manufacture concerned with securing and maintaining sterile condition): Sterile Spray Catheter—used for lavage, spraying of a medical solution or contrast medium, Sterile Cytology Brush, Sterile Fixed Wire Balloon (ABC Dilatation Balloon Catheter, Rapide™ Multistage Dilatation Balloon Catheter) use in adult and adolescent populations to endoscopically dilate strictures of the esophagus for transient use

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, Jiangsu Province, 210032, P.R.China

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 26 September 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 September 2022
Issue 12. 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.

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Micro-Tech (Nanjing) Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 12

Detailed scope

Sterile Non Vascular Stent (Biliary Stent, Esophageal Stent, Intestinal Stent, Tracheal Stent)
Sterile medical devices used for clinical endoscopic procedure including Sterile Dilation Balloon (Disposable Dilation Balloon , Disposable Multistage Dilation Balloon Catheter), Sterile Disposable Hot Biopsy Forceps, Sterile Injection Needle, Sterile Nasal Biliary Drainage Set, Sterile Hot Snare Sterile Stone Extraction Basket, Sterile Cold Snare, Non Vascular sterile Hydro Slide Guidewire, Sterile Biliary Drainage Catheter, Biliary Drainage Catheter Introducer System, Biliary Drainage Catheter with Introducer System, Sterile Biliary Stone Retrieval Balloon Catheter, Sterile Repositionable Hemostasis Clipping Device to be intended for short term use Sterile Pancreatic Pseudocyst Stent with Delivery System to be intended for short term use in the body within 30 days, Sterile Sphincterotome, Non sterile OXY CO₂ Bite Block used to protect the endoscope insertion tube and oesophageal dilators from being bitten by the patient. Sterile Biliary Nitinol Stent Set, short-wire compatible Class I (Sterility aspects only Restricted to the aspects of manufacture concerned with securing and maintaining sterile condition): Sterile Spray Catheter—used for lavage, spraying of a medical solution or contrast medium, Sterile Cytology Brush, Sterile Fixed Wire Balloon (ABC Dilatation Balloon Catheter, Rapide™ Multistage Dilatation Balloon Catheter) use in adult and adolescent populations to endoscopically dilate strictures of the esophagus for transient use

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, Jiangsu Province, 210032, P.R. China

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Certificate CN13/20559

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

ISO 13485:2016 EN ISO 13485:2016



For the following activities

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

This certificate is valid from 26 September 2019 until 26 September 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 September 2022
Issue 10. Certified since 26 September 2013

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

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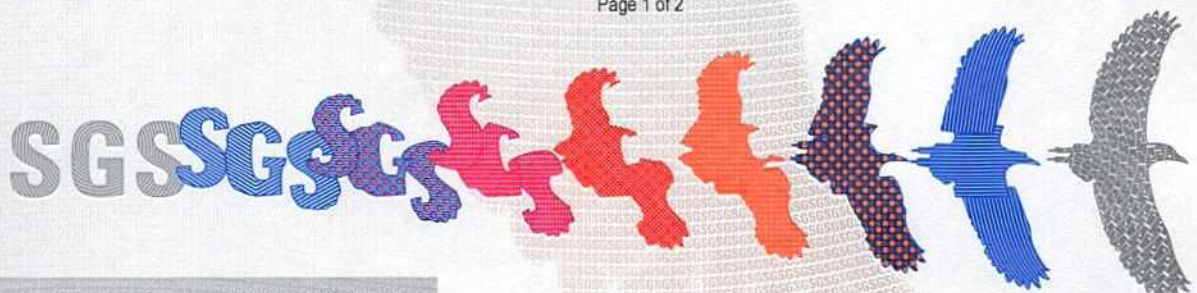


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HC SGS 13485 2016 0118 M2

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Micro-Tech (Nanjing) Co., Ltd.

ISO 13485:2016 EN ISO 13485:2016



Issue 10

Detailed scope

Design and Manufacture of Sterile Cytology Brush, Dilation Balloon(Disposable Dilation Balloon, Disposable Multistage Dilation Balloon Catheter), Disposable Hot Biopsy Forceps, Injection Needle, Nasal Biliary Drainage Set, Non-Vascular Stent, Snare, Spray Catheter, Stone Extraction Basket, Single-Use Cleaning Brush, Single Use Bite Block, Endoscopy Working Channel Valves, Polyp Collection Kit, Cold Snare (used for clinical endoscopic procedure), Hydro Slide Guidewire (used for clinical endoscopic procedure), Biliary Drainage Catheter and Introducer Systems, Biliary Stone Retrieval Balloon Catheter, Repositionable Hemostasis Clipping Device, Pancreatic Pseudocyst Stent with Delivery System, Sphincterotome, Fixed Wire Balloon (ABC Dilatation Balloon Catheter, Rapide™ Multistage Dilatation Balloon Catheter), Non-sterile OXY CO₂ Bite Block and Sterile Biliary Nitinol Stent Set, short-wire compatible

Provision of Sterilization Service for Medical Devices using Ethylene Oxide Gas in accordance with EN ISO 11135:2014



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Additional facilities

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