



# TECHBITE™ BIOPSY FORCEPS

## FOR CLEAN AND LARGE BIOPSATES

For large and precisely cut biopsies, the Techbite™ forceps from MICRO-TECH are equipped with a special design. The spoons allow a meaningful sample capacity and are characterized by a precise cutting performance. To meet the different clinical requirements the assort-

ment includes forceps with and without spike, as well as with smooth and serrated edge. The thumb ring handle offers optimal control and a clear tactile feeling. In order to protect the working channel and reduce sliding friction, the Techbite™ is completely covered.

## SPECIFIC CHARACTERISTICS

- Large spoon design and precise cuts
- With smooth and serrated cutting edge
- Available with or without spike
- Complete coating reduces sliding friction
- Thumb ring handle for optimal control



## SPECIFICATIONS

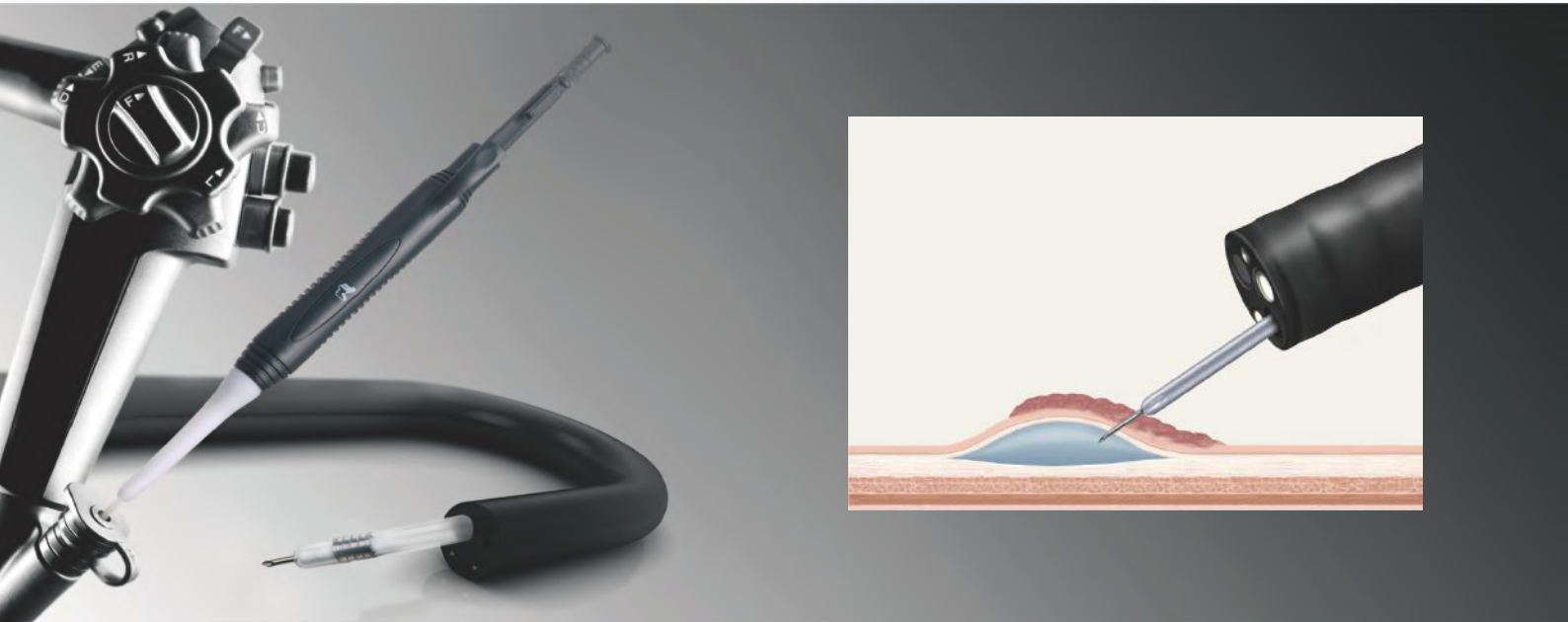
REF	Jaw	Span width jaw mm	Jaw Ø mm	Spike	Working length mm	Covering	Working channel Ø mm
<b>TECHBITE™ BIOPSY FORCEPS</b>							
EBF33-11018120	standard	4.5	1.8	No	1200	blue	2.0
EBF33-11018180	standard	4.5	1.8	No	1800	blue	2.0
EBF33-11018230	standard	4.5	1.8	No	2300	blue	2.0
EBF33-11023120	standard	6.7	2.3	No	1200	blue	2.8
EBF33-11023180	standard	6.7	2.3	No	1800	blue	2.8
EBF33-11023230	standard	6.7	2.3	No	2300	blue	2.8
EBF33-11123120	standard	6.7	2.3	Yes	1200	blue	2.8
EBF33-11123180	standard	6.7	2.3	Yes	1800	blue	2.8
EBF33-11123230	standard	6.7	2.3	Yes	2300	blue	2.8
EBF43-11018120	serrated	4.5	1.8	No	1200	blue	2.0
EBF43-11018180	serrated	4.5	1.8	No	1800	blue	2.0
EBF43-11018230	serrated	4.5	1.8	No	2300	blue	2.0
EBF43-11023120	serrated	6.7	2.3	No	1200	blue	2.8
EBF43-11023180	serrated	6.7	2.3	No	1800	blue	2.8
EBF43-11023230	serrated	6.7	2.3	No	2300	blue	2.8
EBF43-11123120	serrated	6.7	2.3	Yes	1200	blue	2.8
EBF43-11123180	serrated	6.7	2.3	Yes	1800	blue	2.8
EBF43-11123230	serrated	6.7	2.3	Yes	2300	blue	2.8

Packaging unit: 10 pieces

Subject to errors and technical alterations. Rev 09/2019

# Injection Needle

Indications for endoscopy to introduce a sclerosing agent or vasoconstrictor into selected sites to control actual or potential bleeding lesions in the digestive system; and the injection of saline to aid in Endoscopic Mucosal Resection (EMR), polypectomy procedures and to control non-variceal hemorrhage.



## Performance Characteristics

- Lock to ensure that it would not accidentally extend during insertion to damage the scope and to have a stable needle penetration
- Needle release button design, gently press the button to return the needle fully into the sheath for protecting the endoscope from any damage
- Ergonomic handle design: complete needle insertion and withdrawal with one hand



## Specifications

REF	Needle Gauge	Maximum Needle Extension Length (mm)	Sheath O.D. (Fr)	Working Length (mm)	Packaging
Injection Needle					
IN12-194231802	19G	4	7	1800	10/Box
IN12-194231802	19G	5	7	1800	10/Box
IN12-194231802	19G	6	7	1800	10/Box
IN12-194232302	19G	4	7	2300	10/Box
IN12-195232302	19G	5	7	2300	10/Box
IN12-196232302	19G	6	7	2300	10/Box
IN12-224232302	22G	4	7	2300	10/Box
IN12-225232302	22G	5	7	2300	10/Box
IN12-226232302	22G	6	7	2300	10/Box
IN12-254232302	25G	4	7	2300	10/Box
IN12-255232302	25G	5	7	2300	10/Box
IN12-256232302	25G	6	7	2300	10/Box
IN02-224231802	22G	4	7	1800	10/Box
IN02-224232002	22G	4	7	2000	10/Box
IN02-224232302	22G	4	7	2300	10/Box
IN02-225231802	22G	5	7	1800	10/Box
IN02-225232002	22G	5	7	2000	10/Box
IN02-225232302	22G	5	7	2300	10/Box
IN02-226231802	22G	6	7	1800	10/Box
IN02-226232002	22G	6	7	2000	10/Box
IN02-226232302	22G	6	7	2300	10/Box
IN02-254231802	25G	4	7	1800	10/Box
IN02-254232002	25G	4	7	2000	10/Box
IN02-254232302	25G	4	7	2300	10/Box
IN02-255231802	25G	5	7	1800	10/Box
IN02-255232002	25G	5	7	2000	10/Box
IN02-255232302	25G	5	7	2300	10/Box
IN02-256231802	25G	6	7	1800	10/Box
IN02-256232002	25G	6	7	2000	10/Box
IN02-256232302	25G	6	7	2300	10/Box



# 3-LUMEN PAPILOTOME

## FOR PRECISE WIRE GUIDANCE AND CANNULATION

Positioning, cannulation and resection are the decisive features of a safe and successful papillotomy. The 3-lumen papillotome from MICRO-TECH meets these requirements in every way: Emerging from the working channel in the correct position, the atraumatic tip, tapered to 5 Fr, supports cannulation and the resection is done reliably at the "11 o'clock" marker. Maximum safety during resection

is also provided by optional proximal insulation of the cutting wire. The three lumens for cutting wire, guide wire and contrast media provide for a high level of safety and efficient contrast injection. Thanks to the ergonomic 3-ring grip handle, this papillotome is highly user-friendly and easy to control.

### SPECIFIC CHARACTERISTICS

- 3 lumen for guide wire, cutting wire and contrast injection
- Optional insulation of proximal cutting wire
- Cutting direction at 11 o'clock
- Filiform tip, tapered to 5 Fr
- Working length: 2.000 mm
- Outer diameter: 2.5 mm
- Guide wire compatible fully mobile up to 0.035 inch



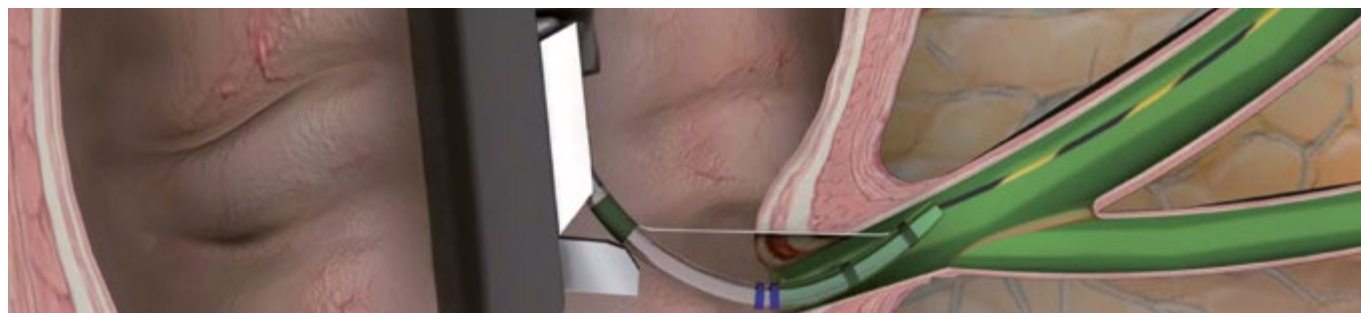
Precise adjustment function



Tip: Precut



Tip: Needle knife



## SPECIFICATIONS

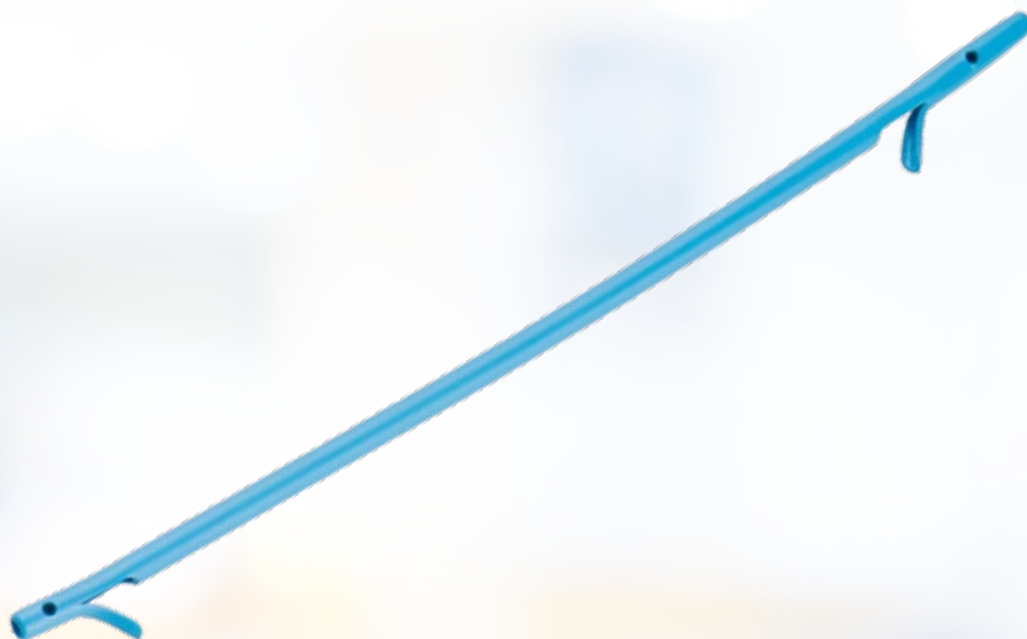
REF	Tip length mm	Cutting wire length mm	Partly insulated cutting wire	Preloaded guide wire	Ø working channel mm
<b>PAPILLOTOME, 3-LUMEN, CONE-TIP</b>					
DSP-30020-111111	0	20	No	No	2.8
DSP-30020-111211	0	20	Yes	No	2.8
DSP-30025-111111	0	25	No	No	2.8
DSP-30025-111211	0	25	Yes	No	2.8
DSP-30030-111111	0	30	No	No	2.8
DSP-30030-111211	0	30	Yes	No	2.8
DSP-30220-111111	2	20	No	No	2.8
DSP-30220-111211	2	20	Yes	No	2.8
DSP-30225-111111	2	25	No	No	2.8
DSP-30225-111211	2	25	Yes	No	2.8
DSP-30230-111111	2	30	No	No	2.8
DSP-30230-111211	2	30	Yes	No	2.8
DSP-30520-111111	5	20	No	No	2.8
DSP-30520-111211	5	20	Yes	No	2.8
DSP-30525-111111	5	25	No	No	2.8
DSP-30525-111211	5	25	Yes	No	2.8
DSP-30530-111111	5	30	No	No	2.8
DSP-30530-111211	5	30	Yes	No	2.8
DSP-30020-111121	0	20	No	Yes	2.8
DSP-30020-111221	0	20	Yes	Yes	2.8
DSP-30025-111121	0	25	No	Yes	2.8
DSP-30025-111221	0	25	Yes	Yes	2.8
DSP-30030-111121	0	30	No	Yes	2.8
DSP-30030-111221	0	30	Yes	Yes	2.8
DSP-30220-111121	2	20	No	Yes	2.8
DSP-30220-111221	2	20	Yes	Yes	2.8
DSP-30225-111121	2	25	No	Yes	2.8
DSP-30225-111221	2	25	Yes	Yes	2.8
DSP-30230-111121	2	30	No	Yes	2.8
DSP-30230-111221	2	30	Yes	Yes	2.8
DSP-30520-111121	5	20	No	Yes	2.8
DSP-30520-111221	5	20	Yes	Yes	2.8
DSP-30525-111121	5	25	No	Yes	2.8
DSP-30525-111221	5	25	Yes	Yes	2.8
DSP-30530-111121	5	30	No	Yes	2.8
DSP-30530-111221	5	30	Yes	Yes	2.8
<b>PAPILLOTOME, 3-LUMEN, NEEDLE KNIFE</b>					
DSP-30505-121111	0	5	No	No	2.8
DSP-30505-121211	0	5	Yes	No	2.8
DSP-30507-121111	0	7	No	No	2.8
DSP-30507-121211	0	7	Yes	No	2.8

Recommended guide wires 0.035": MTN-BM 89/45-A (straight), 600358-5 (straight), 600359-5 (J-Tip)

Recommended guide wires 0.025": MTN-BM 63/26-A (straight) and 600384-5 (straight)

Packaging unit: 2 pieces





# PLASTIC BILE DUCT STENTS

## MAXIMUM DRAINAGE, MAXIMUM HOLD

MICRO-TECH offers a comprehensive range of plastic stents for short and medium-term drainage in the bile duct. The stents are available in different shapes, lengths and diameters. Thus, the ideal stent is available for each indication. The high-quality PE-/PTFE-material of the stents ensures reliable drainage and adapts optimally

to the anatomy of the patient. Flaps at the ends of the stents also ensure a secure hold with minimal migration. For rapid and safe implantation, the stents are available both individually and on pre-loaded systems. In addition, MICRO-TECH also offers introduction-systems in all relevant sizes.

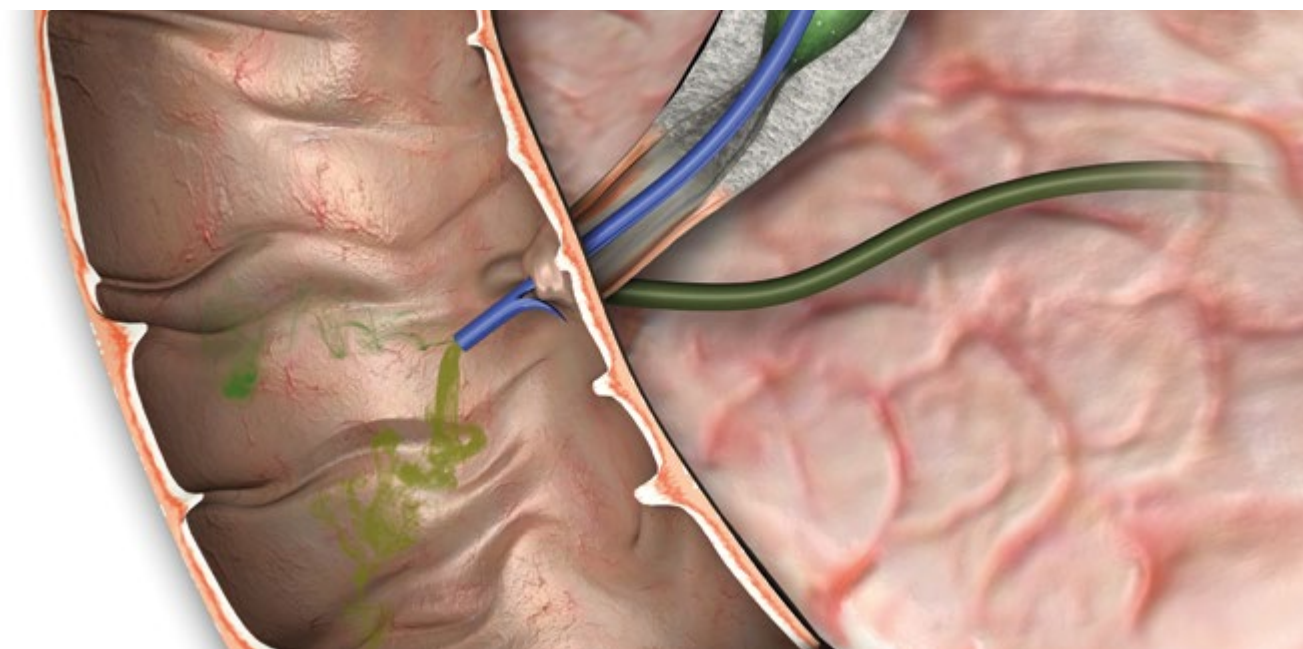
### SPECIFIC CHARACTERISTICS

- Different shapes: straight, curved, angled, pigtail, double-pigtail
- Optimum flow rate
- Ideal adaptation to anatomy
- Safe hold, minimal migration
- Available single-packed or pre-loaded on introduction-system
- High x-ray visibility



Pre-loaded stent

System handle



## SPECIFICATIONS

### STENT STRAIGHT



- Shape: straight
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

Working length	Diameter bile duct prosthesis			
	7FR	8.5FR	10FR	11.5FR
5 cm	BPDS-31114-0705	BPDS-31114-0805	BPDS-31114-1005	BPDS-31114-1105
6 cm	BPDS-31114-0706	BPDS-31114-0806	BPDS-31114-1006	BPDS-31114-1106
7 cm	BPDS-31114-0707	BPDS-31114-0807	BPDS-31114-1007	BPDS-31114-1107
8 cm	BPDS-31114-0708	BPDS-31114-0808	BPDS-31114-1008	BPDS-31114-1108
9 cm	BPDS-31114-0709	BPDS-31114-0809	BPDS-31114-1009	BPDS-31114-1109
10 cm	BPDS-31114-0710	BPDS-31114-0810	BPDS-31114-1010	BPDS-31114-1110
11 cm	BPDS-31114-0711	BPDS-31114-0811	BPDS-31114-1011	BPDS-31114-1111
12 cm	BPDS-31114-0712	BPDS-31114-0812	BPDS-31114-1012	BPDS-31114-1112
13 cm	BPDS-31114-0713	BPDS-31114-0813	BPDS-31114-1013	BPDS-31114-1113
14 cm	BPDS-31114-0714	BPDS-31114-0814	BPDS-31114-1014	BPDS-31114-1114
15 cm	BPDS-31114-0715	BPDS-31114-0815	BPDS-31114-1015	BPDS-31114-1115



# DAILYSNARE

## MORE COMFORT AND RELIABILITY IN EVERYDAY HOSPITAL ROUTINE

In order to make the removal of polyps in everyday hospital routine as efficient as possible, MICRO-TECH has developed a program of disposable polypectomy snares which perfectly combines quality with cost effectiveness. Each oval snare is made of a specially stranded wire, with enhanced radial force, high dimensional stability and precise cutting properties. The 3-ring handle offers a secure hold and transmits every movement reliably to the snare.

### SPECIFIC CHARACTERISTICS

- Very comfortable to use
- Reliable and safe
- Innovative HF-connection
- Ergonomic 3-ring handle
- Excellent cutting properties
- High strength of shape

### SUCCESSFUL IN PRACTICAL USE

The special stranded wire of DailySnare endows the snare with the radial force it needs to open and be controlled in any position, easily and reliably. DailySnare has proved its worth as a reliable solution in daily routine work owing to its enormous dimensional stability and good cutting properties. Thanks to the new handle the snare can easily be opened and closed even if connected to the HF-cable.



### SPECIFICATIONS

REF	Catheter Ø mm	Length mm	Snare Ø mm	Snare type
POLYPECTOMY SNARES				
PFS01-01023230	2.3	2300	10	Oval
PFS01-01523230	2.3	2300	15	Oval
PFS01-02023230	2.3	2300	20	Oval
PFS01-02423230	2.3	2300	24	Oval
PFS01-03623230	2.3	2300	36	Oval
PFS01-12423230	2.3	2300	24	Hexagonal
PFS01-22423230	2.3	2300	24	Crescent
PFS01-33023230	2.3	2300	10/ 20/ 30	3 in 1 vario

Packaging unit: 10 pieces



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

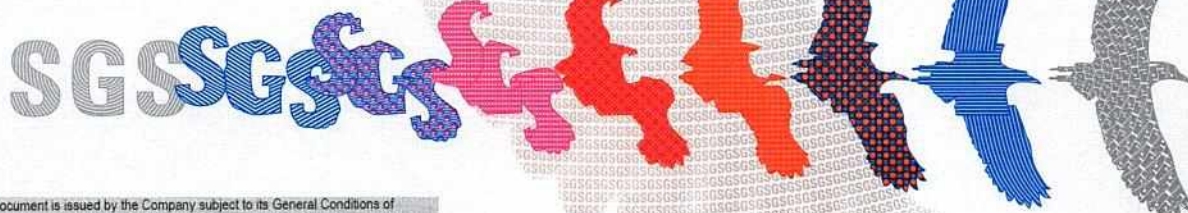


SGS Belgium NV, Notified Body 1639

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

Page 1 of 2



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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 CO<sub>2</sub> 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.

Authorised by

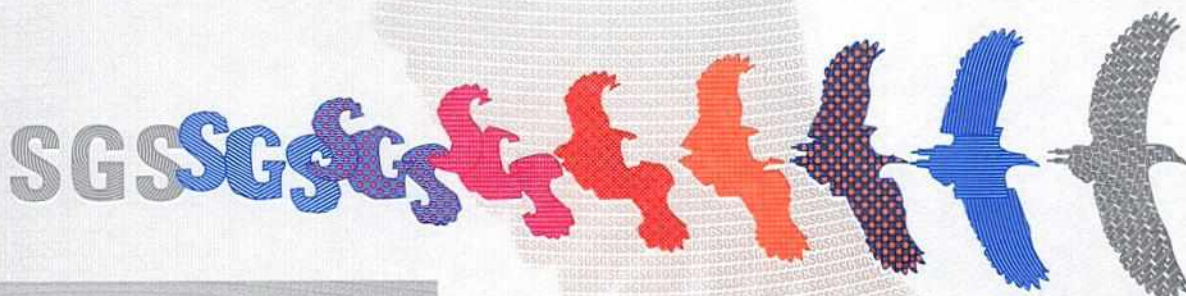
*Jonathan M. Hall*

**SGS United Kingdom Ltd, Notified Body 0120**

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SGS CE 02 0315 M2

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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 CO<sub>2</sub> 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**

Certificate CN13/20559

SGS

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 27 September 2022 until 26 September 2025 and remains valid subject to satisfactory surveillance audits.

Issue 13. Certified since 26 September 2013

Certified activities performed by additional sites are listed on subsequent pages.

*Jonathan M. Hall*

Authorised by  
Jonathan Hall  
Global Head - Certification Services

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Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
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# Micro-Tech (Nanjing) Co., Ltd.

## ISO 13485:2016

## EN ISO 13485:2016

Design and Manufacture of Sterile Cytology Brush, Dilation Balloon (Disposable Dilation Balloon, Disposable Multistage Dilation Balloon Catheter), Disposable Hot Biopsy Forceps, Injection Needle, 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), 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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Certificate CN13/20559, continued

# Micro-Tech (Nanjing) Co., Ltd.

# SGS

ISO 13485:2016

EN ISO 13485:2016

Issue 13
<b>Sites</b>
Micro-Tech (Nanjing) Co., Ltd. No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, 210032, Jiangsu Province, P.R. China
Micro-Tech (Nanjing) Co., Ltd. No. 199. Medicine Valley Avenue, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, P.R.China



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