



3-LUMEN PAPILOTOME

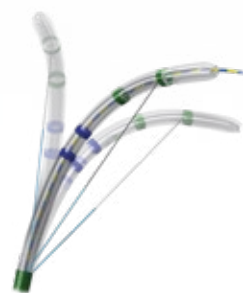
FOR PRECISE WIRE GUIDANCE AND CANNULATION

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



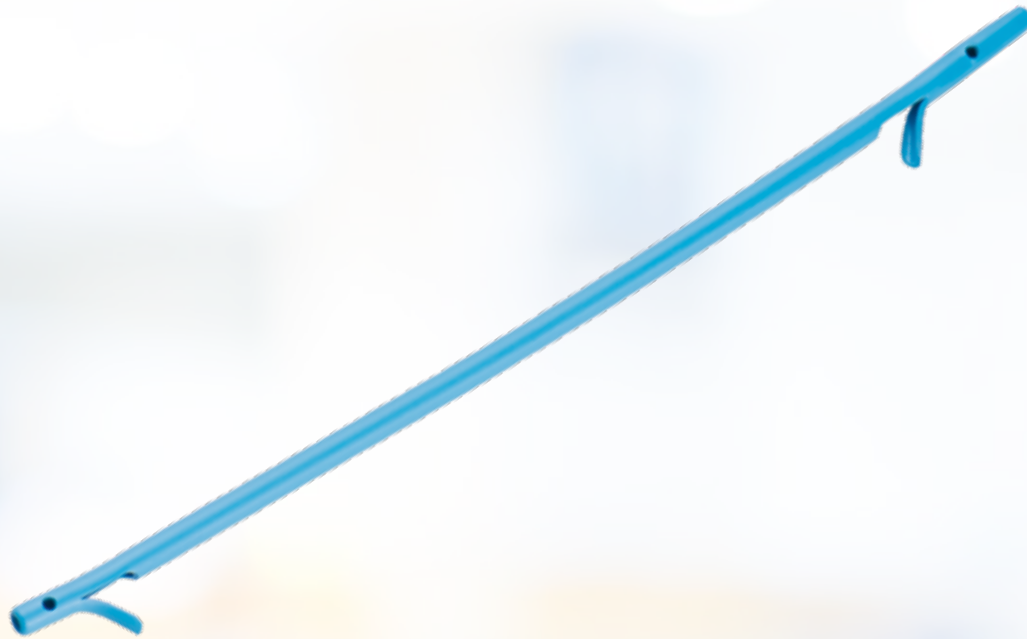
SPECIFICATIONS

REF	Tip length mm	Cutting wire length mm	Partly insulated cutting wire	Preloaded guide wire	Ø working channel mm
PAPILLOTOME, 3-LUMEN, CONE-TIP					
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
PAPILLOTOME, 3-LUMEN, NEEDLE KNIFE					
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.

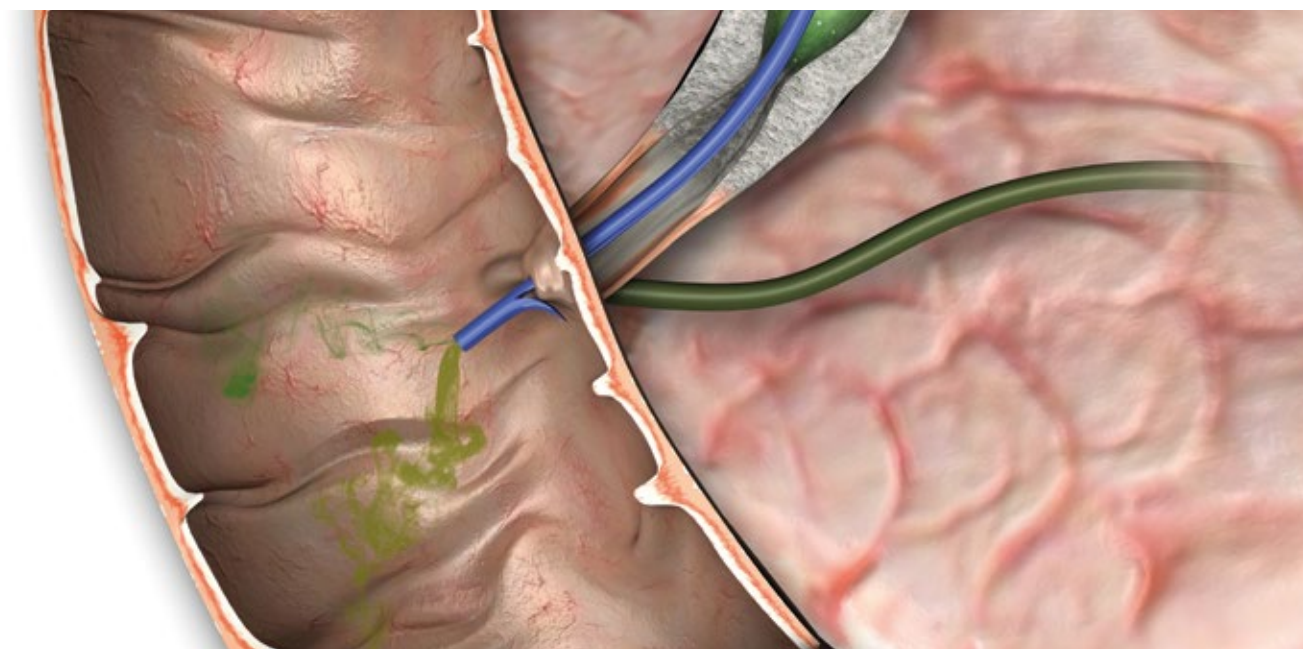
SPECIFIC CHARACTERISTICS

- 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

SPECIFICATIONS

STENT CURVED



- Shape: 15° curved
- 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-32114-0705	BPDS-32114-0805	BPDS-32114-1005	BPDS-32114-1105
6 cm	BPDS-32114-0706	BPDS-32114-0806	BPDS-32114-1006	BPDS-32114-1106
7 cm	BPDS-32114-0707	BPDS-32114-0807	BPDS-32114-1007	BPDS-32114-1107
8 cm	BPDS-32114-0708	BPDS-32114-0808	BPDS-32114-1008	BPDS-32114-1108
9 cm	BPDS-32114-0709	BPDS-32114-0809	BPDS-32114-1009	BPDS-32114-1109
10 cm	BPDS-32114-0710	BPDS-32114-0810	BPDS-32114-1010	BPDS-32114-1110
11 cm	BPDS-32114-0711	BPDS-32114-0811	BPDS-32114-1011	BPDS-32114-1111
12 cm	BPDS-32114-0712	BPDS-32114-0812	BPDS-32114-1012	BPDS-32114-1112
13 cm	BPDS-32114-0713	BPDS-32114-0813	BPDS-32114-1013	BPDS-32114-1113
14 cm	BPDS-32114-0714	BPDS-32114-0814	BPDS-32114-1014	BPDS-32114-1114
15 cm	BPDS-32114-0715	BPDS-32114-0815	BPDS-32114-1015	BPDS-32114-1115

SPECIFICATIONS

STENT LATERAL ANGLED



- Form: 45° lateral angled
- 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-33114-0705	BPDS-33114-0805	BPDS-33114-1005	BPDS-33114-1105
6 cm	BPDS-33114-0706	BPDS-33114-0806	BPDS-33114-1006	BPDS-33114-1106
7 cm	BPDS-33114-0707	BPDS-33114-0807	BPDS-33114-1007	BPDS-33114-1107
8 cm	BPDS-33114-0708	BPDS-33114-0808	BPDS-33114-1008	BPDS-33114-1108
9 cm	BPDS-33114-0709	BPDS-33114-0809	BPDS-33114-1009	BPDS-33114-1109
10 cm	BPDS-33114-0710	BPDS-33114-0810	BPDS-33114-1010	BPDS-33114-1110
11 cm	BPDS-33114-0711	BPDS-33114-0811	BPDS-33114-1011	BPDS-33114-1111
12 cm	BPDS-33114-0712	BPDS-33114-0812	BPDS-33114-1012	BPDS-33114-1112
13 cm	BPDS-33114-0713	BPDS-33114-0813	BPDS-33114-1013	BPDS-33114-1113
14 cm	BPDS-33114-0714	BPDS-33114-0814	BPDS-33114-1014	BPDS-33114-1114
15 cm	BPDS-33114-0715	BPDS-33114-0815	BPDS-33114-1015	BPDS-33114-1115

SPECIFICATIONS

STENT CENTRAL ANGLED



- Shape: 90° central angled
- 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-34114-0705	BPDS-34114-0805	BPDS-34114-1005	BPDS-34114-1105
6 cm	BPDS-34114-0706	BPDS-34114-0806	BPDS-34114-1006	BPDS-34114-1106
7 cm	BPDS-34114-0707	BPDS-34114-0807	BPDS-34114-1007	BPDS-34114-1107
8 cm	BPDS-34114-0708	BPDS-34114-0808	BPDS-34114-1008	BPDS-34114-1108
9 cm	BPDS-34114-0709	BPDS-34114-0809	BPDS-34114-1009	BPDS-34114-1109
10 cm	BPDS-34114-0710	BPDS-34114-0810	BPDS-34114-1010	BPDS-34114-1110
11 cm	BPDS-34114-0711	BPDS-34114-0811	BPDS-34114-1011	BPDS-34114-1111
12 cm	BPDS-34114-0712	BPDS-34114-0812	BPDS-34114-1012	BPDS-34114-1112
13 cm	BPDS-34114-0713	BPDS-34114-0813	BPDS-34114-1013	BPDS-34114-1113
14 cm	BPDS-34114-0714	BPDS-34114-0814	BPDS-34114-1014	BPDS-34114-1114
15 cm	BPDS-34114-0715	BPDS-34114-0815	BPDS-34114-1015	BPDS-34114-1115

SPECIFICATIONS

PIGTAIL DOUBLE O-SHAPE



- Shape: Pigtail O-Shape
- Double
- 4 side-holes
- X-ray visible
- Material: PE

Working length	Diameter bile duct prosthesis		
	7FR	8.5FR	10FR
5 cm	BPDS-31003-0705	BPDS-31003-0805	BPDS-31003-1005
6 cm	BPDS-31003-0706	-	-
7 cm	BPDS-31003-0707	BPDS-31003-0807	BPDS-31003-1007
8 cm	-	BPDS-31003-0808	-
9 cm	BPDS-31003-0709	-	BPDS-31003-1009
10 cm	BPDS-31003-0710	-	BPDS-31003-1010
11 cm	-	BPDS-31003-08011	BPDS-31003-1011
12 cm	BPDS-31003-0712	-	BPDS-31003-1012
15 cm	BPDS-31003-0715	-	-

SPECIFICATIONS

PIGTAIL DISTAL



- Shape: Pigtail
- Distal
- 2 side-holes
- X-ray visible
- Material: PE

Working length	Diameter bile duct prosthesis	
	8.5FR	10FR
5 cm	BPDS-31196-0805	BPDS-31196-1005
6 cm	BPDS-31196-0806	BPDS-31196-1006
7 cm	BPDS-31196-0807	BPDS-31196-1007
8 cm	BPDS-31196-0808	BPDS-31196-1008
9 cm	BPDS-31196-0809	BPDS-31196-1009
10 cm	BPDS-31196-0810	BPDS-31196-1010
11 cm	BPDS-31196-0811	BPDS-31196-1011
12 cm	BPDS-31196-0812	BPDS-31196-1012
13 cm	BPDS-31196-0813	BPDS-31196-1013
14 cm	BPDS-31196-0814	BPDS-31196-1014
15 cm	BPDS-31196-0815	BPDS-31196-1015

SPECIFICATIONS

PIGTAIL PROXIMAL



- Shape: Pigtail
- Proximal
- 2 side-holes
- X-ray visible
- Material: PE

Working length	Diameter bile duct prosthesis	
	8.5FR	10FR
5 cm	BPDS-31916-0805	BPDS-31916-1005
6 cm	BPDS-31916-0806	BPDS-31916-1006
7 cm	BPDS-31916-0807	BPDS-31916-1007
8 cm	BPDS-31916-0808	BPDS-31916-1008
9 cm	BPDS-31916-0809	BPDS-31916-1009
10 cm	BPDS-31916-0810	BPDS-31916-1010
11 cm	BPDS-31916-0811	BPDS-31916-1011
12 cm	BPDS-31916-0812	BPDS-31916-1012
13 cm	BPDS-31916-0813	BPDS-31916-1013
14 cm	BPDS-31916-0814	BPDS-31916-1014
15 cm	BPDS-31916-0815	BPDS-31916-1015

INTRODUCER-SYSTEMS WITHOUT STENT

SPECIFICATIONS



- One step introducer-system
- X-ray visible

New: Extended guide catheter

REF	Ø catheter	Guide catheter	Introducer length
BPDI-0740/22	7 FR	40 cm	220 cm
BPDI-0840/22	8.5 FR	40 cm	220 cm
BPDI-1040/22	10 FR	40 cm	220 cm
BPDI-1140/22	11.5 FR	40 cm	220 cm

INTRODUCER-SYSTEMS WITH PRE-LOADED STENT



- One step introducer-system
- X-ray visible

SPECIFICATIONS

STENT STRAIGHT



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

REF	Ø catheter	Stent working/ total length	Introducer length
BPDS-31114-0805/22	8.5 FR	5 / 7 cm	220 cm
BPDS-31114-0807/22	8.5 FR	7 / 9 cm	220 cm
BPDS-31114-0809/22	8.5 FR	9 / 11 cm	220 cm
BPDS-31114-0811/22	8.5 FR	11 / 13 cm	220 cm
BPDS-31114-1005/22	10 FR	5 / 7 cm	220 cm
BPDS-31114-1007/22	10 FR	7 / 9 cm	220 cm
BPDS-31114-1009/22	10 FR	9 / 11 cm	220 cm
BPDS-31114-1011/22	10 FR	11 / 13 cm	220 cm

SPECIFICATIONS

STENT CURVED



- Shape: 15° curved
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

REF	Ø catheter	Stent working/ total length	Introducer length
BPDS-32114-0805/22	8.5 FR	5 / 7 cm	220 cm
BPDS-32114-0807/22	8.5 FR	7 / 9 cm	220 cm
BPDS-32114-0809/22	8.5 FR	9 / 11 cm	220 cm
BPDS-32114-0811/22	8.5 FR	11 / 13 cm	220 cm
BPDS-32114-1005/22	10 FR	5 / 7 cm	220 cm
BPDS-32114-1007/22	10 FR	7 / 9 cm	220 cm
BPDS-32114-1009/22	10 FR	9 / 11 cm	220 cm
BPDS-32114-1011/22	10 FR	11 / 13 cm	220 cm

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.

Authorised by

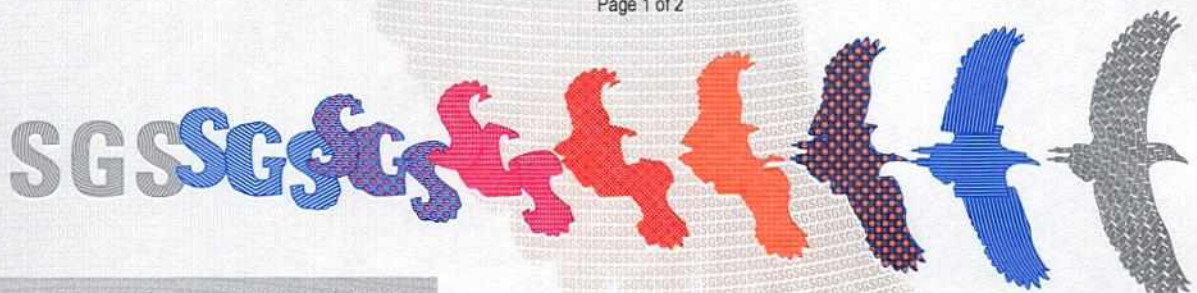


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Micro-Tech (Nanjing) Co., Ltd.

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

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

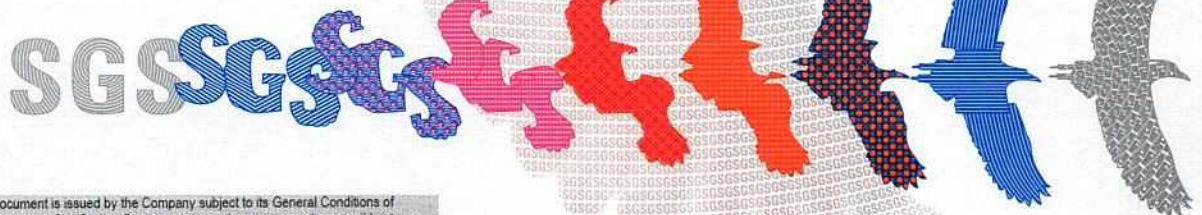
Authorised by

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.

Authorised by

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SGS CE 02 0315 M2

Page 1 of 2



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