

Accessories.

Clever equipment for smart endoscopy.

MICRO-TECH has a close cooperation with the company Medgic – a member of the MICRO-TECH Group. The brand Medgic represents useful instruments of a high quality making daily routine endoscopy convenient and more safe. The product range includes de-

vices that offer work protection to doctors and nurses as well as textiles which increase the patient comfort. All Medgic solutions are naturally certified according to **EN ISO 13485** and fulfill the stringent requirements of directive 93/42 EEC concerning medical devices.



Disposable Mouthguards

Different models are available: standard, pediatric and mouthguards with a special a traumatic design



Disposable Coloshorts

Soft and absorbent dark blue material, rear opening that can be closed by Velcro strips, rubber waistband for easy fit



Disposable sterile instrument cloth

Light blue water resistant and absorbent cloth with either 4 transparent instrument pockets – rear adhesive tape for fixation



Disposable biopsy valve with flush connection

Suitable for Olympus and Fujifilm endoscopes



Disposable channel valves

The channel valves fit on Olympus and Pentax endoscopes



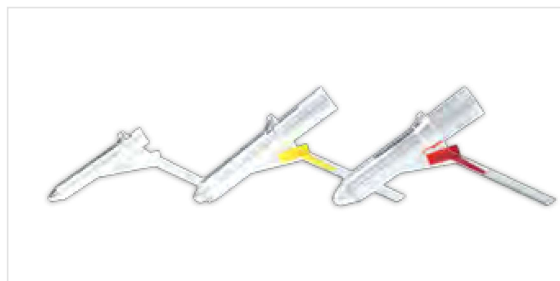
Polyp trap

The 4-chamber system enables the separate capture of up to 4 polyps or biopsy material



Single-use proctoscope.

For a reliable diagnosis of the rectum MICRO-TECH disposes different proctoscopes in a disposable variant. The proctoscopes are made of high quality clear acrylic, which ensures a clear view of the intestinal wall and avoids cold sensations for the patient during insertion. The smooth surface facilitates the examination and prevents potential injuries.



REF	Description	Length mm	Ø outside mm	Ø inside mm
Proctoscope				
RA1480	Size S for paediatrics, color: white	80	14	12
RA2295	Size M, color: yellow	95	22	20
RA2695	Size L, color: red	95	26	24

RA0001 Adapter for cold-light-source

Packaging unit: Proctoscopes: 100 pieces / Cold-light-adapter: 1 piece

REF	Description	Measurements
Mouthguards		
AC01-101.M	Disposable mouthguard, yellow, latex free rubber strap	Medium (M)
AC01-102.M	Disposable mouthguard, yellow, NO strap	Medium (M)
AC01-103.A	Disposable mouthguard, atraumatic design, blue, latex free textile strap	Atraumatic (A)
AC01-103.M	Disposable mouthguard, blue, textile strap	Medium (M)
AC01-103.P	Disposable pediatric mouthguard, latex free textile strap	Pediatric (P)
Coloshorts		
TX01-101.L	Dark blue, Valcro strips at back, rubber waistband, size L	50/132/29 cm (waistband*/bottom/leg) Leg length 60 cm
TX01-101.XL	Dark blue, Valcro strips at back, rubber waistband, size XL	56/144/35 cm (waistband*/bottom/leg) Leg length 64 cm
Instrument cloth		
TX03-101.M4	Light blue, 4 pockets (l x w: 20 x 25 cm each)	90 x 70 cm
Biopsy valves		
AC03-101.O	Blue, for Olympus and Fujifilm endoscopes (G5 and higher)	
AC03-101.P	Red, for Pentax endoscopes	
AS2450000	Disposable biopsy valve with flush connection, suitable for Olympus and Fujifilm endoscopes	
Polyp trap		
BBP-50	Polyp trap with 4-chamber	

*cm of relaxed waistband, stretchable up to bottom size



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

SGS United Kingdom Ltd, Notified Body 0120

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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

Page 2 of 2

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

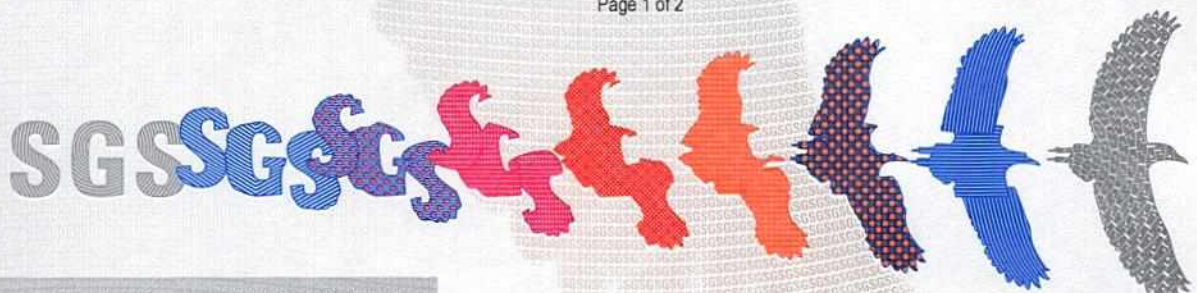


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HC SGS 13485 2016 0118 M2

Page 1 of 2



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

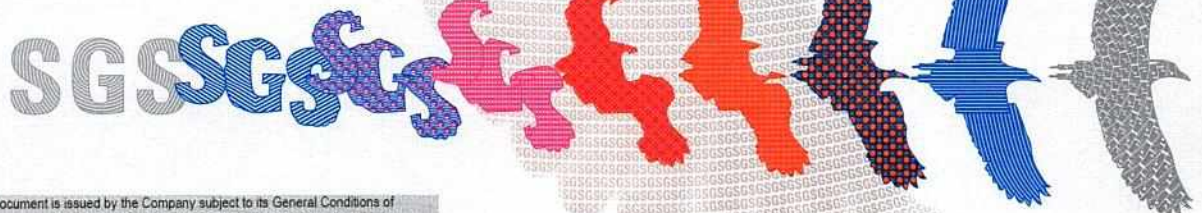
Authorised by

SGS Belgium NV, Notified Body 1639

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

Page 1 of 2



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