MICRO-TECH™
ENDOSCOPY

ENDOSCOPY ACCESSORIES

OPTIMALLY EQUIPPED FOR EVERY INTERVENTION

MICRO-TECH provides you optimally with products around endoscopy. The product range includes devices that offer work protection to doctors and nurses as well as textiles which increase patient comfort. All solutions are naturally certified according to EN ISO 13485 and fulfill the stringent requirements of directive 93/42 EEC concerning medical devices.

YOUR TRUSTED PARTNER IN ENDOSCOPY

DISPOSABLE MOUTHGUARDS

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

DISPOSABLE COLOSHORTS

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

DISPOSABLE BIOPSY VALVE WITH FLUSH CONNECTION

Suitable for Olympus and Fujifilm endoscopes

DISPOSABLE CHANNEL VALVES

The channel valves fit on Olympus and Pentax endoscopes

SPECIFICATIONS

REF	Description	Measurements
MOUTHGUARDS		
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)
AC01-150	Disposable textile strap, blue (also available separately)	
COLOSHORTS		
TX01-101.L	Dark blue, Valcro strips at back, rubber waistband, size: unisex	50/132/29 cm (waistband*/bottom/leg) Leg length 60 cm
BIOPSY VALVES		
AC03-102.O	Blue, for Olympus and Fujifilm endoscopes (G5 and higher)	
AC03-102.P	Red, for Pentax endoscopes	
AS2450000	Disposable biopsy valve with flush connection, suitable for Olympus and Fujifilm endoscopes	
AS2460000	Disposable biopsy valve with flush connection, suitable for Pentax endoscopes	

*cm of relaxed waistband, stretchable up to bottom size

MICRO-TECH™ ENDOSCOPY

MICRO-TECH Europe GmbH
Mündelheimer Weg 48
40472 Düsseldorf | Germany

P +49 (0)211 73 27 626-0 | F +49 (0)211 73 27 626-99
contact@micro-tech-europe.com
www.micro-tech-europe.com

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
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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_2 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

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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 048850 0048 Rev. 02

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):

Grasping Forceps,
Retrieve Net,
Disposable Balloon Inflation Device,
Guidewire Locking Device,
Endoscopic Distal Attachment

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH1921727

Valid from: 2020-01-10
Valid until: 2024-05-26

Date, 2020-01-10

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

TÜV®

A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 048850 0048 Rev. 02

Facility(ies):

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

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

.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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