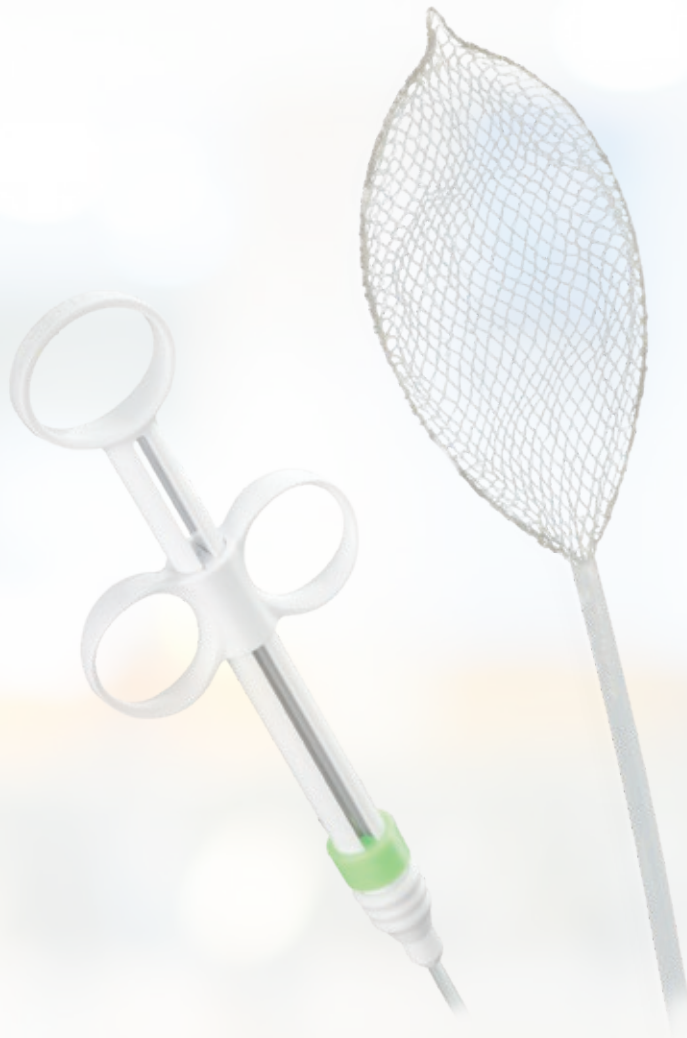




NETS

SAFELY REMOVE FOREIGN BODIES AND POLYPS

The MT net has been developed for the removal of polyps and foreign bodies and enables the reliable recovery of tissue samples. The net itself consists of a reinforced thread material, which offers additional safety during recovery. Thanks to its unique dimensional stability and large opening, it facilitates work over several passes.

Twister® Plus is a 360° rotatable net that allows polyps or foreign objects to be easily and safely removed. In the large, three-dimensional mesh, several polyps and foreign objects can be detected simultaneously in one pass. The material is tear-resistant and of high quality. Four net sizes and three system lengths are available. Twister® Plus thus offers the ideal solution for every requirement.

SPECIFIC CHARACTERISTICS

- Large net
- High quality manufacture
- Comfortable 3-ring handle
- Easy and precise opening



Twister® Plus in different net sizes

Shape stable MT net

SPECIFICATIONS

REF	Ø net mm	Ø catheter mm	Working length mm	Ø working channel mm
TWISTER® PLUS				
HIC-GDL-27-5	22	2.5	230	2.8
HIC-GDL-26-5	26	2.5	230	2.8
HIC-GDL-29-5	32	2.5	230	2.8
HIC-GDL-30-5	15	1.7	120	2.0
HIC-GDL-31-5	15	1.7	160	2.0

Packaging unit: 5 pieces

REF	Ø net mm	Snare	Working length mm	Ø working channel mm
RETRIEVAL NET				
NT-E-30/23-P	30	Oval	2300	2.8
NT-E-30/16-P	30	Oval	1600	2.8

Packaging unit: 2 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

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

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

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <https://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

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

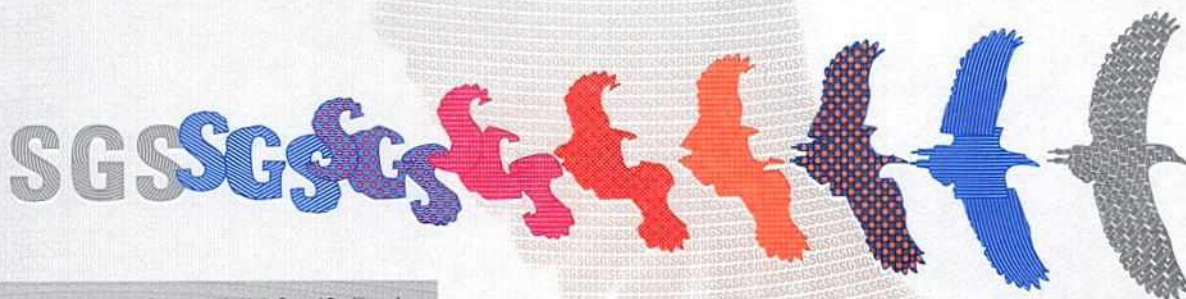
Jonathan M. Hall

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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

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

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



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.



This document is an authentic electronic certificate for Client* business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



Certificate CN13/20559, continued

Micro-Tech (Nanjing) Co., Ltd.

SGS

ISO 13485:2016

EN ISO 13485:2016

Issue 13
Sites
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



This document is an authentic electronic certificate for Client* business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

