

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

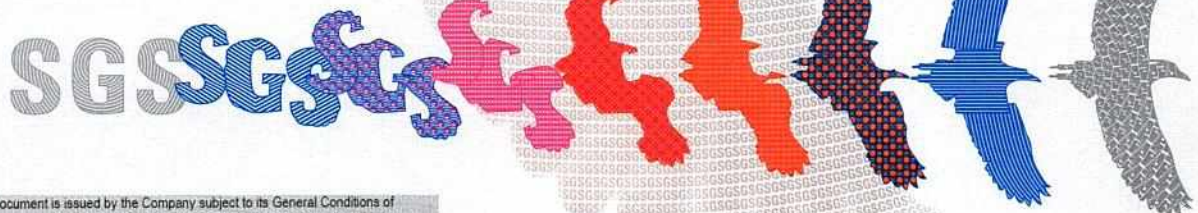
Authorised by

**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 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

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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



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.

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.

**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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