

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

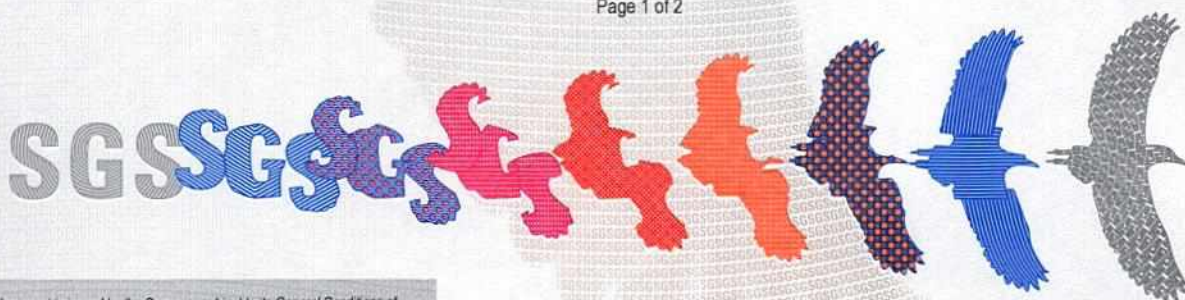



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SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

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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**