

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  
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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.

# SGS

ISO 13485:2016

EN ISO 13485:2016

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| Issue 13  |
| <b>Sites</b>  |
| Micro-Tech (Nanjing) Co., Ltd.<br>No. 10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, 210032, Jiangsu Province, P.R. China       |
| Micro-Tech (Nanjing) Co., Ltd.<br>No. 199. Medicine Valley Avenue, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, P.R.China |



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