

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 13485:2003 EN ISO 13485:2012

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 5 January 2017 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 31 March 2019

Issue 8. Certified since 26 September 2013

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

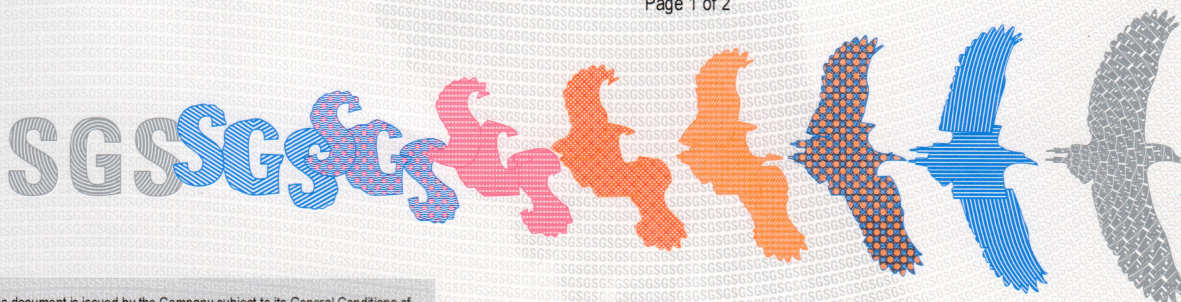
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SGS 13485-2 0614 M2

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Micro-Tech (Nanjing) Co., Ltd.

ISO 13485:2003
EN ISO 13485:2012



Issue 8

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
Provision of Sterilization Service for Medical Devices using Ethylene Oxide Gas in accordance with EN ISO 11135:2014

Additional facilities

No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, P.R. China



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