



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 048850 0052 Rev. 03

Holder of Certificate: **Micro-Tech (Nanjing) Co., Ltd.**

No. 10 Gaoke Third Road
Nanjing National Hi-Tech Industrial Development Zone
210032 Nanjing, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design, Development, Production and Distribution of Sterile and Non-sterile General Non-active, Non-implantable Medical Devices
Design, Development, Production and Distribution of Sterile Non-active Implants
Design, Development, Production and Distribution of Sterile General Active Medical Devices.
For detail information see page 4.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 048850 0052 Rev. 03

Report No.: SH25021701

Valid from: 2025-08-19

Valid until: 2027-05-31

Date, 2025-08-19

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s):

ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

Micro-Tech (Nanjing) Co., Ltd.

No. 10 Gaoke Third Road, Nanjing National Hi-Tech Industrial
Development Zone, 210032 Nanjing, Jiangsu Province, PEOPLE'S
REPUBLIC OF CHINA

Production of Sterile Non-active Instruments:

Disposable Dilation Balloon, Disposable Multistage Dilation
Balloon Catheter

Production of Sterile Non-active Implants:

Esophageal Stent, Biliary Stent, Tracheal Stent, Intestinal Stent

Production of Sterile active Surgical Devices:

Sterile Sphincterotome

Production of Sterile Non-active Instruments :

Ovum Pick-up Needle



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Micro-Tech (Nanjing) Co., Ltd.

No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech
Industrial Development Zone, 210032 Nanjing, Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA

Design, Development, Production and Distribution of Sterile Non-active Instruments:

Single-Use Biopsy Forceps, Grasping Forceps, Retrieve Net, Endoscopic Ultrasound Aspiration Needle, Extraction Basket I short-wire compatible, Single Use MultiClip Device, Injection Needle, Stone Extraction Basket, Sterile Repositionable Hemostasis Clipping Device, Sterile Cold Snare, Cytology Brush, Spray Catheter, Endoscopic Distal Attachment, Disposable Dilator Brush, Polyp Collection Kit, Multiple Band Ligator Set, Sterile Biliary Drainage Catheter,

Sterile Biliary Drainage Catheter Introducer System, Sterile Biliary Drainage Catheter with Introducer System, Indigo Carmine, Disposable Dilatation Balloon, Disposable Multistage Dilatation Balloon Catheter, Sterile Biliary Stone Retrieval Balloon Catheter, Sterile Fixed Wire Balloon (Dilatation Balloon Catheter, Multistage Dilatation Balloon Catheter), Retrieval Balloon I short-wire compatible, Sterile Hydro Slide Guidewire

Design, Development, Production and Distribution of Sterile Non-active Implants:

Esophageal Stent, Biliary Stent, Tracheal Stent, Intestinal Stent, Rapid Exchange Biliary Stent System, Sterile Pancreatic Pseudocyst Stent with Delivery System

Design, Development, Production and Distribution of Sterile Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools

Single-Use Marked Spring Tip Guidewire, Guidewire Locking Device, Biliary Drainage Catheter Set I short-wire compatible

Distribution of Sterile Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools: Disposable Balloon Inflation Device

Design, Development, Production and Distribution of Sterile active Surgical Devices:

Single Use Electrosurgical Knife, Disposable Hot Biopsy Forceps, Sterile Snare, Single-Use Coagulation Forceps, Sphincterotome I short-wire compatible, Sterile Sphincterotome

Design, Development, Production and Distribution of Non-Sterile Non-active Instruments:

Non-sterile OXY CO₂ Bite Block, Single-Use Cleaning Brush, Endoscopy Working Channel Valves, Single-Use Bite Block, Transport Pad



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Design, Development, Production and Distribution of Sterile Non-active Instruments:

Multiple Band Ligator Set, Endoscopic Ultrasound Aspiration Needle, Retrieval Balloon I short-wire compatible, Extraction Basket I short-wire compatible, Nasal Biliary Drainage Set; Stone Extraction Basket, Sterile Hydro Slide Guidewire, Sterile Biliary Drainage Catheter, Sterile Biliary Drainage Catheter Introducer System, Sterile Biliary Drainage Catheter with Introducer System, Disposable Dilation Balloon, Disposable Multistage Dilation Balloon Catheter, Sterile Biliary Stone Retrieval Balloon Catheter; Sterile Fixed Wire Balloon (Dilatation Balloon Catheter, Multistage Dilatation Balloon Catheter), Indigo Carmine GI Marker, Single-Use Biopsy Forceps, Grasping Forceps, Retrieve Net; Single Use MultiClip Device, Injection Needle, Sterile Repositionable Hemostasis Clipping Device, Sterile Cold Snare, Cytology Brush, Spray Catheter, Endoscopic Distal Attachment, Disposable Dilator Brush, Polyp Collection Kit

Design, Development, Production and Distribution of Sterile Non-active Implants:

Esophageal Stent; Biliary Stent, Tracheal Stent, Intestinal Stent, Rapid Exchange Biliary Stent System, Sterile Pancreatic Pseudocyst Stent with Delivery System

Design, Development, Production and Distribution of Sterile active Surgical Devices:

Single Use Electrosurgical Knife, Sphincterotome I short-wire compatible, Sterile Sphincterotome, Disposable Hot Biopsy Forceps, Sterile Snare, Single-Use Coagulation Forceps

Design, Development, Production and Distribution of Non-Sterile Non-active Instruments:

Non-sterile OXY CO₂ Bite Block, Single-Use Cleaning Brush, Endoscopy Working Channel Valves, Single-Use Bite Block, Transport Pad

Production of Sterile Non-active Instruments:

Ovum Pick-up Needle

Distribution of Sterile Non-active Non-implantable Guide Catheters, Balloon Catheters, Guidewires, Introducers, Filters, and Related Tools:

Disposable Balloon Inflation Device

Design, Development, Production and Distribution of Sterile Non-active Non-implantable Guide Catheters, Balloon Catheters, Guidewires, Introducers, Filters, and Related Tools:

Guidewire Locking Device, Biliary Drainage Catheter Set I short-wire compatible, Single-Use Marked Spring Tip Guidewire