



Certificate

No. Q5 098565 0005 Rev. 01

Holder of Certificate:

**Suzhou Lantex Medical
Technology Company Limited**
Building 7, 58 Xinting Road, High-tech Industrial Zone
215151 Suzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design, Development, Production and Distribution of
Single Use Intraluminal Circular Stapler,
Single Use Circular Stapler for Rectal Prolapse
and Haemorrhoids,
Single Use Reloadable Linear Stapler and Reloads,
Single Use Reloadable Linear Cutter Stapler and Reloads,
Single Use Endoscopic Linear Cutter Stapler and Reloads,
Single Use Transverse Cutting Linear Stapler and Reloads,
Single Use Suction and Irrigation System,
Single Use Anoscope Kit, Single Use Clipping Device,
Single Use Biopsy Forceps,
Single Use Endoscopic Cytology Brush,
Single Use Endoscopic Stone Retrieval Basket,
Single Use Stone Extraction Balloon,
Single Use Non-Vascular Guidewire,
Single Use Balloon Dilatation Catheter,
Single Use Multi-Channel Port System
Single Use Snare, Single Use Sphincterotome,
Single Use Injection Needle Catheter,
Single Use Spray Catheter,
Single Use Nasal Biliary Drainage Catheter,
Single Use Three-stage Balloon Dilatation Catheter,
Single Use Specimen Bag, Single Use Trocar,
Single Use Purse String Forceps

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). See also notes overleaf.

Report No.: SH20117401
Valid from: 2020-07-31
Valid until: 2023-07-11

Date, 2020-07-31

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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