

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

# Certificate

No. Q5 086250 0016 Rev. 01

**Holder of Certificate:** Ningbo Luke Medical Devices Co., Ltd.

Gujiayan, Yangming Road  
315400 Yuyao City, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

Design, Development, Production and Distribution of Disposable Infusion Pumps, Urethral Catheters (Silicone), Natural Latex Rubber Condoms, Drainage Tubes, Wound Drainage Systems and Anesthesia Masks.

Production and Distribution of Laryngeal Mask Airways, Stomach Tubes, Endotracheal Tubes, Oxygen Masks, Suction Catheters, Nasal Oxygen Cannulas, Breathing Circuits, Heat and Moisture Exchangers, Breathing System Filters, Manual Resuscitators, Infusion Sets with Precision Filters for Single Use, Oropharyngeal Airways, Double Lumen Endobronchial Tubes, Single-Use Anesthesia Kits, Urinary Catheterization Collection Kits, Suction Reservoirs, Drainage Bag, Sterile Surgical Pack, Disposable Endobronchial Blocker Tubes, Spacer for Aerosols, Catheter Mounts, Suction Tubing with Yankauer Handle, Nebulizer Masks, Tracheostomy Tubes, Nasopharyngeal Airways, Silicone Loops and Catheter Fixation Devices.

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.:** SH1965101  
**Valid from:** 2020-02-28  
**Valid until:** 2023-01-03

**Date,** 2020-02-28

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):** Ningbo Luke Medical Devices Co., Ltd.  
Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province,  
PEOPLE'S REPUBLIC OF CHINA

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