



Certificate

No. Q5 086250 0016 Rev. 03

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 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, Medical Heat and Moisture Exchangers, Breathing System Filters, Manual Resuscitators, Oropharyngeal Airways, Double Lumen Endobronchial Tubes, Suction Reservoirs, Drainage Bag, 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, Medical Protective Goggles, Medical Face Shields, CPR mask.

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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 086250 0016 Rev. 03

Report No.: SH2265101
Valid from: 2023-05-15
Valid until: 2026-01-03

Date, 2023-05-15



Christoph Dicks
Head of Certification/Notified Body

**DAkkS**Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 086250 0016 Rev. 03**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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See Scope of Certificate