



Product Service

CERTIFICATE

No. Q1N 16 11 86250 010

Holder of Certificate: Ningbo Luke Medical Devices Co., Ltd.Gujaiyan, 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 Pump, Urethral Catheters (Silicone), Natural Latex Rubber Condom Production and Distribution of Laryngeal Mask Airways, Stomach Tubes, Drainage Tubes, Endotracheal Tubes, Oxygen Masks, Suction Catheters, Nasal Oxygen Cannulas, Disposable Breathing Circuits, Heat and Moisture Exchangers, Breathing System Filters, Manual Resuscitators, Wound Drainage Systems, 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

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.: SH1665107

Valid from: 2017-02-06

Valid until: 2020-01-03

Date, 2017-02-06

Stefan Preiß



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Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

Facility(ies): Ningbo Luke Medical Devices Co., Ltd.
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