Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 086250 0018 Rev. 01

Manufacturer:

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

Product Category(ies):

**Laryngeal Mask Airways,
Stomach Tubes, Drainage Tubes,
Endotracheal Tubes, Oxygen Masks,
Suction Catheters, Nasal Oxygen Cannulas,
Breathing Circuits,
Heat and Moisture Exchangers,
Breathing System Filters,
Manual Resuscitators,
Wound Drainage Systems,
Infusion Sets with Precision Filters for Single-Use,
Double Lumen Endobronchial Tubes,
Single-Use Anesthesia Kits,
Urinary Catheterization Collection Kits,
Disposable Endobronchial Blocker Tubes,
Anesthesia Masks, Catheter Mounts,
Suction Tubing with Yankauer Handle,
Nebulizer Masks, Tracheostomy Tubes.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19651EXT01

Valid from: 2020-01-08
Valid until: 2024-05-26

Date, 2020-01-08

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Facility(ies):

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

CANACK TECHNOLOGY LTD.
Room 1308-2, Building A, Huaxing Times Square, No. 478
Wensan Road, Xihu District, 310007 Hangzhou City, Zhejiang
Province, PEOPLE'S REPUBLIC OF CHINA

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