



Product Service

Confirmation Statement on validity of EC Certificate (MDD)
pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 086250 0021 Rev. 00

Manufacturer:

Ningbo Luke Medical Devices Co., Ltd.

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

**This Confirmation Statement
is only valid in combination
with the following
EC Certificate (MDD):**

G2 086250 0018 Rev. 01

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer
data initiated 26 May 2021 or later.

The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for
placing devices on the market and putting into service apply. For details and confirmation statement
validity see: [www.tuvsud.com/ps-cert?q=cert:GCQ 086250 0021 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:GCQ_086250_0021_Rev._00)

Report No.:

SH2265101

Valid until:

2024-05-26

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2023-05-15

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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,
Double Lumen Endobronchial Tubes,
Disposable Endobronchial Blocker Tubes,
Anesthesia Masks, Catheter Mounts,
Suction Tubing with Yankauer Handle,
Nebulizer Masks, Tracheostomy Tubes.

**Description of
Change:**

Reduction of product category(ies):
Infusion Sets with Precision Filters for Single-Use,
Urinary Catheterization Collection Kits, Single-Use
Anesthesia Kits

Reduction of facility: CANACK TECHNOLOGY LTD.
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478 Wensan Road, Xihu District 310007 Hangzhou City,
Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA