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Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 086250 0024 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): **G2S 086250 0019 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 0024 Rev. 00

Report No.: SH2265101

Valid until: 2024-05-26

Issue Date: 2023-05-15

Christoph Dicks
Head of Certification/Notified Body

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Product Category(ies): **Oropharyngeal Airways,**
Suction Reservoirs,
Drainage Bags,
Nasopharyngeal Airways,
Catheter Fixation Devices,
Spacer for Aerosols, Silicone Loops.

Description of Change:

Reduction of product category(ies): Sterile Surgical Packs.

Reduction of facility: 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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