



EC CERTIFICATE

Production Quality Assurance

Certificate No.: 267558-2018-CE-ARE-NA-PS Rev 1.0 Project No.: PRJC-559887-2017-MSL-AZE Valid Until: 27 May 2024

This is to certify that the quality system of:

**KNGMED MEDİKAL ELEKTRONİK SAĞLIK HİZMETLERİ
VE KİMYASAL MADDELER İTHALAT VE İHRACAT
TİCARET LİMİTED ŞİRKETİ**

29 Ekim Mah. 10007 Sk. No:26/B Menemen/Izmir/Turkey

For production and final product inspection/testing of:

**Breathing and Anesthesia Masks, Sterile Internal Nasal Splints, Sodalime
(Carbon Dioxide Absorbent)**

Has been assessed with respect to:

**The conformity assessment procedure described in Annex V of Council
Directive 93/42/EEC on Medical Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 21 May 2021

For the issuing office:
**Notified Body 2460
DNV Product Assurance AS**

Check Validity



Hazem Tinawi
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f1, rev.0

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	24 June 2019
1.0	Address Change	21 May 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Breathing and Anesthesia Masks	Non-sterile Silicone Anaesthesia mask, <ul style="list-style-type: none"> • Size-00, 01, 02, 03, 04 & 05 Non-sterile Nasal CPAP Masks <ul style="list-style-type: none"> • Small, Medium, Large Non-sterile Fullface CPAP/ Bi-PAP and Ventilation Masks <ul style="list-style-type: none"> • Small, Medium, Large 	Ila
Nasal Splints	Sterile Silicone Internal Nasal Splint - Integral Airway & Bi-Valve	Is
Sodalime	Non-sterile Sodalime (Carbon Dioxide Absorbent)	Ila

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
KNGMED MEDİKAL ELEKTRONİK SAĞLIK HİZMETLERİ VE KİMYASAL MADDELER İTHALAT VE İHRACAT TİCARET LİMİTED ŞİRKETİ	29 Ekim Mah. 10007 Sk. No:26/B Menemen/Izmir/Turkey

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate



CERTIFICATE

**KNGMED MEDİKAL ELEKTRONİK SAĞLIK
HİZMETLERİ VE KİMYASAL MADDELER
İTHALAT VE İHRACAT LİMİTED ŞİRKETİ**

**29 EKİM MAH. 10007. SOK. NO:26B
MENEMEN / İZMİR / TÜRKİYE**

Has been assessed and found to Comply with the Requirements of:

ISO 13485:2016

Medical Devices-Quality Management System is applicable to:

**PRODUCTION AND SALES OF RESPIRATORY AND ANESTHESIA MASKS,
STERILE INNER NASAL SPLINTS, SODA LIME (CARBON DIOXIDE
ABSORBER) FOR THE MEDICAL INDUSTRY**

Certificate Number: 2021/MDQMS/10558/01 Initial Certification Date: 13.12.2021

Certification Period: 3 Years

Certificate Validity Date: 12.12.2022



IQR Sertifikasyon Onayı

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

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