



EC Certificate

Full Quality Assurance System

Certificate No.:
267558-2018-CE-ARE-NA-PS

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

Cinar San. Sit. 10001 Sok No: 28/A-10 Ulukent Menemen, Izmir,
35663 - 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, 24 June 2019



For:
DNV GL PRESAFE AS

D. Palani

Palani Damodharan

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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



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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

Products covered by this Certificate:

Product Description	Product Name	Class
Breathing and Anesthesia Masks	Non-sterile Silicone Anaesthesia mask, • Size-00, 01, 02, 03, 04 & 05 Non-sterile Nasal CPAP Masks • Small, Medium, Large Non-sterile Fullface CPAP/ Bi-PAP and Ventilation Masks • 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 Medikal, Sağlık, Hiz. ve Kimyasal Madde İth. İhr. Tic. Ltd. Şti (-)	Cinar San. Sit. 10001 Sok No: 28/A-10 Ulukent Menemen, Izmir,,35663,-,Turkey



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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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate





CERTIFICATE

Certification No : 4390/KNG13A
Initial Certification Date : 02.03.2018
Recertification Date : --
Issue Date : 24.01.2020
Expiration Date : 01.03.2021
Revision Date / No : 24.01.2020/ 02

RoyalCert International Registrars, certifies that the management system of the organization has been assessed and found to be in accordance with the requirements of the related standard.

ISO 13485:2016

**KNGMED MEDİKAL ELEKT. SAĞ. HİZ. VE KİMYASAL MAD. İTH.
İHR. TİC. LTD. ŞTİ**

29 Ekim Mah. 10007 Sk. No:26/B Ulukent Sanayi Bölgesi / MENEMEN / İZMİR

Scope: *Manufacturing, Sterilization and Distribution of Anaesthesia Emergency and Intensive Care Device*

Operation Manager
Carolin Höfner



D-2M-18590-01-00



This certification was conducted in accordance with the RoyalCert auditing and certification procedures and is subject to regular surveillance audits.
The original certificate contains a security hologram.
Certification period is 3 years. Verifiable at: www.royalcert.com

RoyalCert International Registrars GmbH
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