



*full face mask*

# full face mask



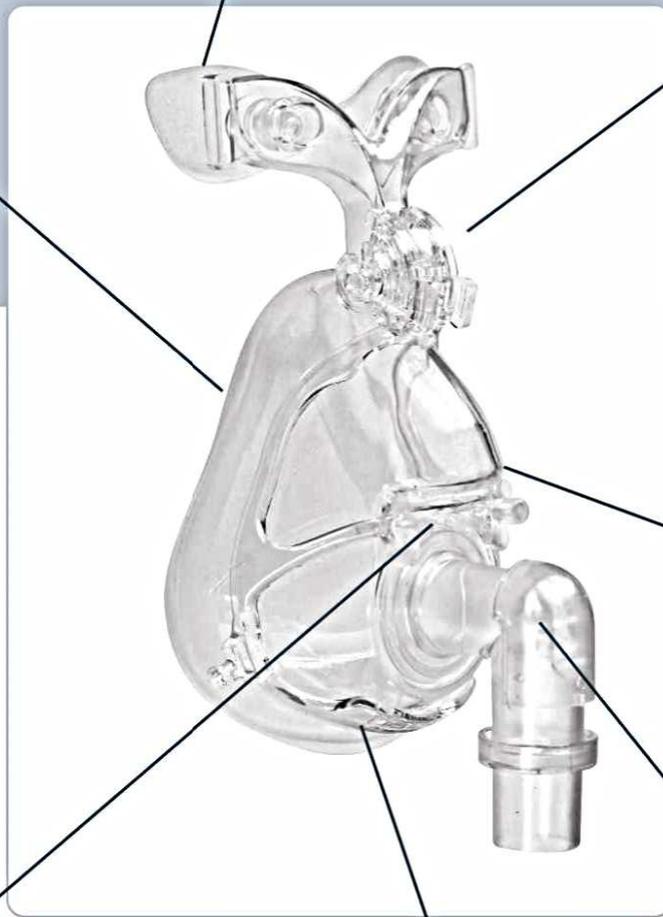
Silicone Head Support



Adjustable polycarbonate head support



Double Frame Silicone Body



Breatheable Foam Headgear



Reinforced Polycarbonate Frame



Oxygen and Pressure Port



Exhalation Port



Nonvented Elbow Connector for noninvasive ventilator usage

# full face mask

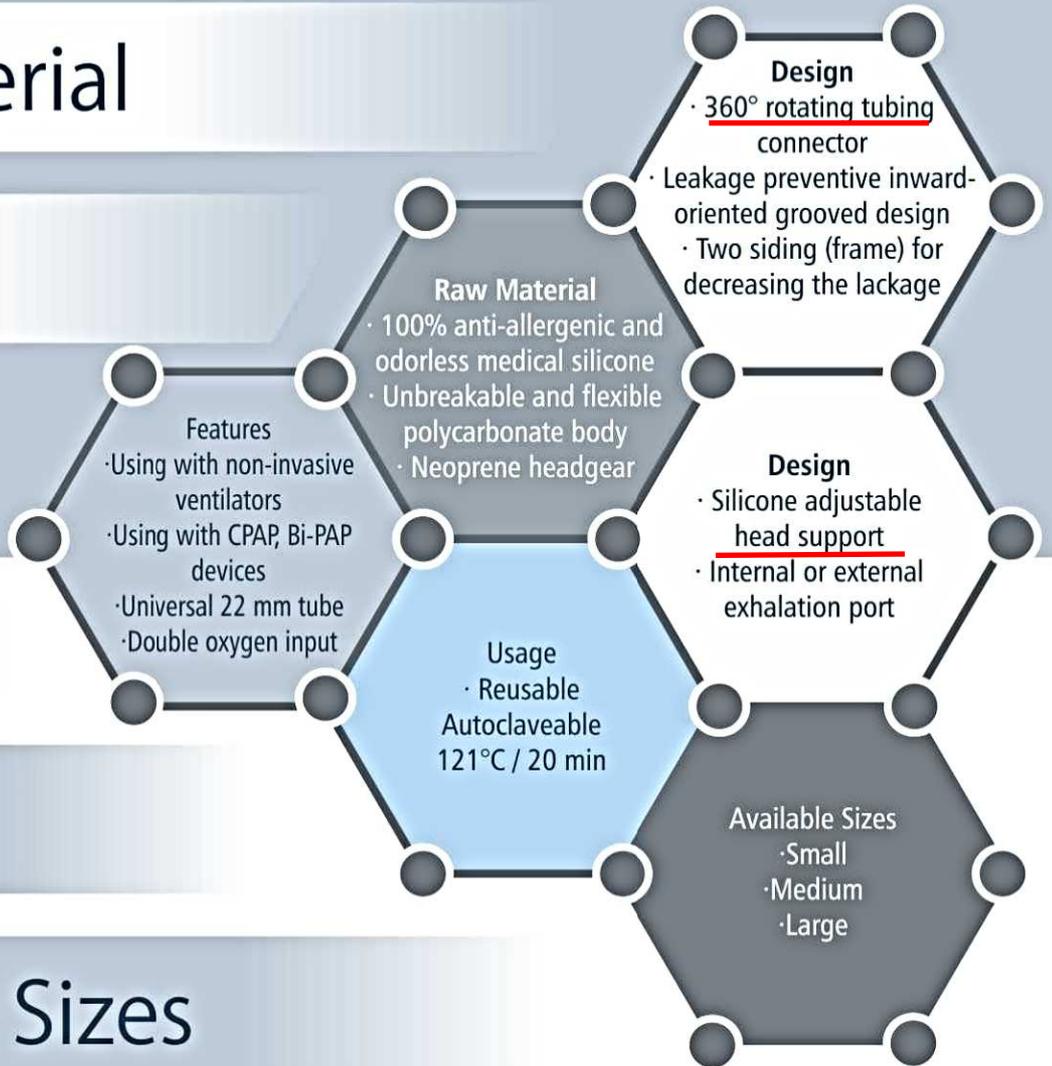
## Raw Material

## Features

## Design

## Usage

## Available Sizes



### Available Sizes (Small, Medium, Large)

- |                         |   |
|-------------------------|---|
| 1. SemiVent (item no):  | #7600040-S<br>#7600040-M<br>#7600040-L        |
| 2. NonVented (item no): | #7600041-S<br>#7600041-M<br>#7600041-L        |
| 3. Vented (item no):    | #7600042-S<br>#7600042-M<br><u>#7600042-L</u> |





*full face*

**KNGMED**  
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10001 Sokak No.28 / A - 10

Çınar Sanayi Sitesi

Ulukent / Menemen / İzmir / TÜRKİYE

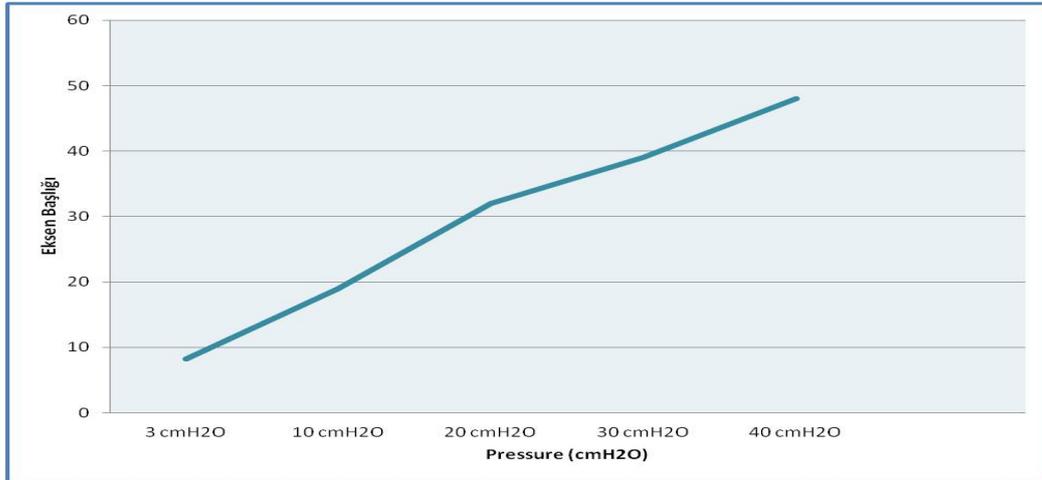
<b>NAME OF THE MANUFACTURER</b>	KNGMED MEDİKAL ELEKTRONİK SAĞLIK HİZMETLERİ VE KİMYASAL MADDELER İTHALAT İHRACAT ve TİCARET LİMİTED ŞİRKETİ			
<b>ADDRESS</b>	29 EKİM MAH. 10007 SOK. NO:26/B MENEMEN/İZMİR-TURKEY			
<b>PRODUCT CODE</b>	7600040-S 7600040-M 7600040-L	7600041-S 7600041-M 7600041-L	7600042-S 7600042-M 7600042-L	
<b>PRODUCT BRAND NAME</b>	KNGMED ORA-NASAL			
<b>PRODUT GENERIC NAME</b>	ORA-NASAL CPAP BIPAP VPAP MASK			
<b>PRODUCT COMMERCIAL NAME</b>	ORA-NASALCPAP MASK			
<b>INTENDED USE</b>	Masks are intended for use by people whom the CPAP, Bi-PAP therapy is prescribed by a healthcare professional or respiratory therapist. Masks are for single-patient use at home or in a hospital/healthcare setting. In order to ensure the correct use of masks at home, in the hospital/health institution environment, cooperation should be made with the doctor and healthcare personel.			
<b>PRODUCT DESCRIPTION</b>	The Ora-Nasal Mask (222 Series) channels airflow from ventilator/Positive Air Pressure(PAP) devices non-invasively to the patients who suffer from obstructive sleep apnea (OSA) or respiratory insufficiency and respiratory failure.			
<b>STERILE / NON STERILE</b>	NON STERILE			
<b>FEATURES OF THE PRODUCT:</b>	TRANSPARENT BODY SOFT SILICONE, NON-ALLERGIC FACE PILLOWS HEAD SUPPORT 4 POINT HEAD GEAR CONNECTION 22MM STANDARD CONNECTOR DIAMETER OXYGEN AND PRESSURE PORT, DIAMETER Ø 4MM SUPPORT STRAP MADE OF ELASTIC MATERIAL, WIDTH 20 MM			
<b>PRODUCT PARTS</b>	SILICONE BREATHING FACE MASK, TRANSPARENT MASK BODY CONNECTOR 90 DEGREES ELBOW HEAD STRAP			
<b>PRODUCT PICTURE</b>				
<b>PRODUCT COMPONENTS</b>	MASK BODY FRAME FACE PILLOW (S-M-L SIZES) ELBOW CONNECTOR MASK CONNECTOR HEAD GEAR HEAD GEAR ATTACHES			
<b>RAW MATERIALS USED IN PRODUCTS</b>	LIQUID SILICONE MASK PILLOW, POLYCARBONATE BODY FRAME, POLYCARBONATE MASK CONNECTOR POLYCARBONATE 90 DEG. ELBOW VELCRO/FOAM HEADGEAR			

	POLYCARBONATE HEADGEAR ATTACHES		
<b>PRODUCT SIZES</b>	SMALL MEDIUM LARGE		
<b>SHELF LIFE AND STORAGE INSTRUCTIONS</b>	ACCORDING TO THE APPLIED STABILITY TESTS THE DEFINED SHELF LIFE IS 5 YEARS. DO NOT LEAVE UNDER DIRECT SUN LIGHT. OPENED OR HARMED PACKAGES SHALL NOT BE USED.		
<b>DURATION OF PRODUCT USAGE</b>	THE PRODUCT REUSABLE		
<b>STERILIZATION METHOD</b>	AUTOCLAVE STERILIZATION AT 121°C FOR 15 MINUTES.		
<b>CLEANING</b>	HAND WASH THE MASK BEFORE FIRST USE AND DAILY. THE HEADGEAR SHOULD BE HAND WASHED WEEKLY, OR AS NEEDED. THE HEADGEAR DOES NOT NEED TO BE REMOVED FOR DAILY CLEANING OF THE MASK. RINSE ALL PARTS WITH CLEAR WATER. ALLOW ALL PARTS TO AIR-DRY. PERFORM A VISUAL INSPECTION. <b>SINGLE PATIENT USE</b>		
<b>DEAD SPACE MEASUREMENT</b>	DEAD SPACE (mL)		
	Small	Medium	Large
	225 mL	236 mL	245 mL
<b>NOISE LEVEL</b>	27dB		
<b>Classification</b>	IIA		
<b>Applicable Standards</b>	EN ISO 14971 EN ISO 17510-2 TS EN 10993-1 EN ISO 13485 Med. Dev. 93/42/EEC		
<b>CERTIFICATION</b>	PRODUCT IS CE CERTIFIED ACCORDING TO 93/42/EEC DIRECTIVE OF EU COMISSION. NOTIFIED BODY : DNV GL PRESAFE AS (NORWAY) CE MARKING ID : 2460 CERTIFICATE NO : 267558-2018-CE-ARE-NA-PS NOTIFIED BODY CONFIRMATION LETTER REF : C693441		

## Technical Data Sheet of Ora-Nasal Masks

### Therapy Pressure-Exhaust Flow Rate:

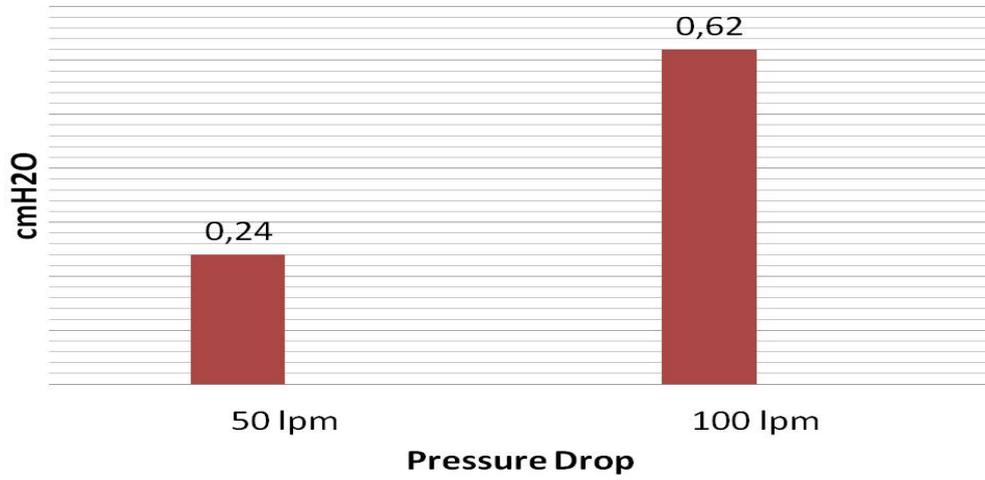
Mask	REF	Exhaust Rate				
		3cmH <sub>2</sub> O	10cmH <sub>2</sub> O	20cmH <sub>2</sub> O	30cmH <sub>2</sub> O	40cmH <sub>2</sub> O
KNGMED	#7600040	8,2	19	32	39	48
Ora-Nasal	#7600041					
Mask	#7600042					



Pressure(cmH2O)

**Pressure Drop:**

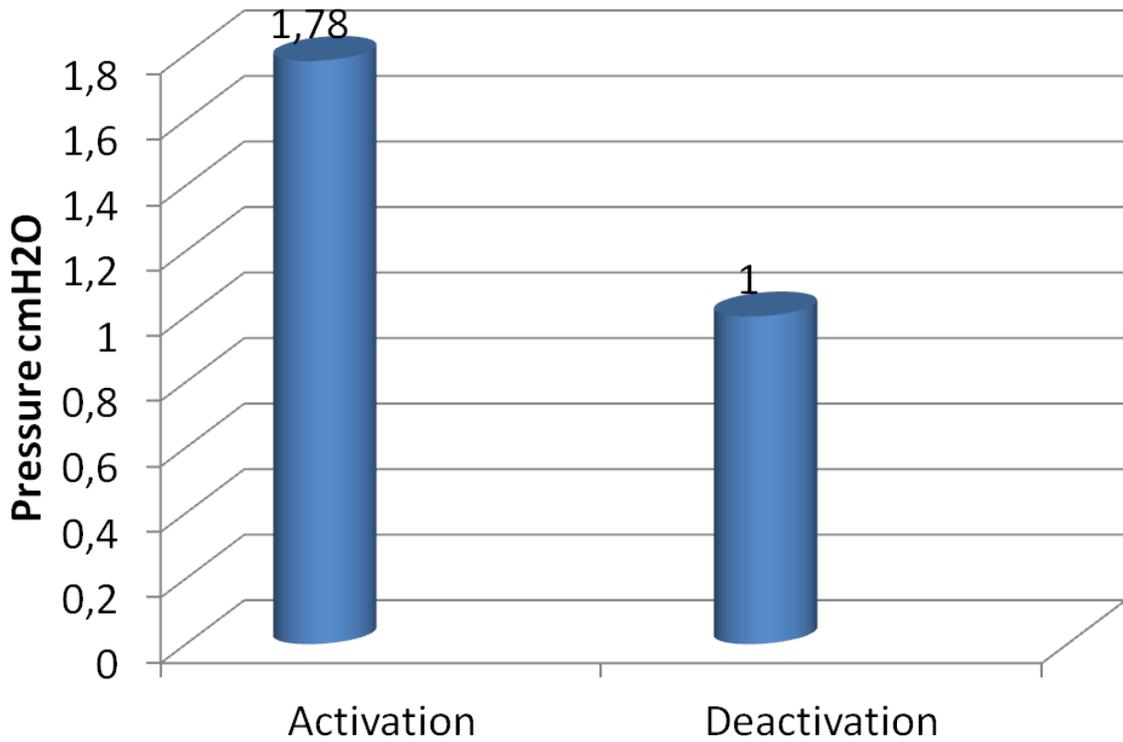
Pressure Drop			
Mask	REF	Flow Rate	
		50L/Min	100L/Min
KNGMED	#7600040	0.24	0.62
Ora-Nasal Mask	#7600041		
	#7600042		

*Pressure Drop Graphic*

**Anti Asphyxia Valve Activation/Deactivation Pressure:**

AAV Pressure Activation/ Deactivation			
Mask	REF	Activation	Deactivation
KNGMED	#7600040	1.73	0.88
Ora-Nasal Mask	#7600042		

AAV Pressure Activation/ Deactivation  
Graphic



\* Tested all pressures are below the minimum pressure rate of CPAP Therapy devices. (<3cmH2O).



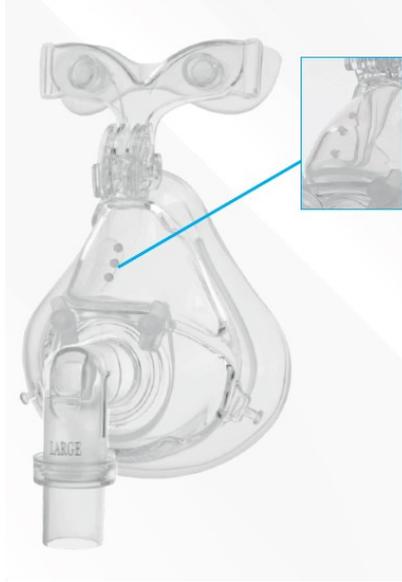
**Kngmed Medical Co Ltd.**  
29 Ekim Mah. 10007 Sk.  
No:26/B  
Menemen/Izmir/Turkey

## Specification of Fullface Masks

### Kngmed FullFace Masks



7600041



**7600042**



7600040

Product Number	
Mask	REF
KNGMED Fullface Mask Standard Elbow	#7600041
KNGMED Fullface Mask EE Elbow	#7600040
KNGMED Fullface Mask EE Elbow with Exhalation	<b>#7600042</b>

Available Sizes	Small, Medium, Large
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**Intended Use**

FullFace Mask is intended to provide an interface for application of CPAP or bi-level or ventilation therapy to patients. This mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The standard elbow (SE) does not have any exhalation port. If the SE elbow is used, it is necessary a separated exhalation port.

**Dead Space** Small: 125 ml, Medium: 151 ml, Large:169 ml,

**Material List**

Face plate: Polycarbonate  
Cushion: Medical Grade silicone  
Port Cap: Silicone  
Elbows: Polycarbonate  
Elbow Split: Polycarbonate  
Headgear Clips: Polycarbonate  
**Headgear: UBL/Foam/Spandex**

**Production**

LSR Injection

**Manufacturer**

Kngmed Medical / Made in Turkey

**Instruction for Use**

Labeling present on each mask

**Standards**

EN ISO 14971  
EN ISO 17510-2  
TS EN 10993-1  
EN ISO 13485  
Med. Dev. 93/42/EEC

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