



TEKNİK DOSYA – TECHNICAL FILE
ÜRÜN & ÜRETİM BİLGİLERİ
PRODUCT & MANUFACTURING INFORMATION

TF – 02

Yayın Tarihi

01.08.2021

Revizyon No

00

Revizyon Tarihi

YÜKSEK KONSANTRASYONLU OKSİJEN MASKESİ, GENİŞ
(High Concentration Oxygen Mask, Elongated)

Ürün Tanımı (Product Information)

High Concentration Oxygen Mask is a soft, transparent, non-sterile and disposable product made of biocompatible PVC. The rubber and nose clip on it allow the mask to be worn comfortably on the face. The connecting tube between the mask and the reservoir is unidirectional. This connecting tube has a valve that prevents gas from entering the reservoir bag from the mask during expiration; therefore, the breath given by the patient does not go to the bag. Only oxygen goes from the bag to the patient. In addition, there are valves on both sides of the mask. These flaps prevent the entry of room air during inspiration and open during expiration, allowing air in the mask to escape. It consists of the parts defined below;

* Mask: It is made of medical grade PVC. It is compatible with the facial features and is ergonomic. There is a mask wire that adapts to the contours of the face and a rubber that provides grip to the face. An under-chin design is available to fit the face size.

* Hose: It is a 200cm connection hose made of PVC, channeled, resistant to breakage and bending.

* Connector: Made of PVC, compatible with the product. There are 2 connectors. It is attached to both ends of the hose with adhesive.

* Adapter: It is high density polyethylene material in white color. By connecting the connector to the plug, the mask connection of the hose is provided. The patient can rotate according to his position.

* Reservoir: Made of white, medical grade PVC. Highly concentrated oxygen fills the reservoir.

* Silicone Valve: It is white colored, silicone material. Thanks to the silicone valves, the pure oxygen in the reservoir is taken by the patient.

Kullanım Amacı (Intended Use)

With its design suitable for facial anatomy, it provides oxygen to the patient with a mask. Pure (High concentration oxygen) fills into the reservoir. Thanks to the silicone valves in the mask, high concentration oxygen is taken by the patient. Oxygen escape is prevented by silicon valves.

Sınıflandırma MDR (AB) 2017/745/ EK

IX

Classification MDR 2017/745 EU Annex

IX

Sınıf IIa, Kural 2

Class IIa, Rule 2

GMDN Kodu & Adı

GMDN Code & Name

35171

Mask, Air/oxygen

Ambalaj

Packing

| Parça Adı | Part Name | Adet |
|-----------------------------------|-----------------------------------|------|
| Oksijen Maskesi | Oxygen Mask | 1 |
| Adaptör | Adapter | 1 |
| Hortum Tubing with two connectors | (iki ucuna da konnektör yapılmış) | 1 |
| Reservoir | | 1 |

The biological evaluation of the product was carried out according to the EN ISO

10993-1 standard. Biological Evaluation Table-1 is as in the Biological Evaluation

Table in EN ISO 10993-1 standard. Based on this table, biocompatibility tests

were made for the main raw material of the product, test reports are in ANNEX-5.

Biyolojik Değerlendirme

Biological Evaluation

| Tipleri Types | Model No, Ref No Model No | Ürün Product | Steril mi? Sterile? | | Sterilizasyon Metodu Sterilization Method | Raf Ömrü Shelf Life |
|--------------------|---------------------------------|-----------------|------------------------|-------------|--|------------------------|
| | | | Evet Yes | Hayır No | | |
| Yetişkin Adult | T20170 | | --- | X | --- | 5 yıl |
| Çocuk Pediatric | T20174 | | --- | X | --- | 5 years |