

	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 yapıştırılmış)	1
Reservoir	1

Biyolojik Değerlendirme Biological Evaluation

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.

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 Çocuk Pediatric	T20170 T20174		---	X	---	5 yıl 5 years

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OKSİJEN MASKESİ (Oxygen Mask)

Ürün Tanımı (Product Information)

Oxygen Mask is a soft, transparent, latex-free (phtalate free), non-sterile or 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. It is used in short-term oxygen therapy. It is transparent so that it is easier to monitor the patient's lip color and vomiting. The holes on both sides allow excess gases to escape, especially during exhalation. 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.
- * Hose: It is a 250cm 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.

Kullanım Amacı (Intended Use)

It is used for oxygenation and ventilation of the lungs of the patient or injured, arranged to include the mouth and nose with its design in accordance with the facial anatomy.

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	Adet
Oksijen Maskesi oxygen mask	1
Adaptör adapter	1
Hortum tubing with two connectors (iki ucuna da konnektör yapıştırılmış)	1

Biyolojik Değerlendirme
Biological Evaluation

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.

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	T20168		X	X	---	5 yıl 5 years
Pediyatrik Pediatric Bebek Infant	T20167 T20166					

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OKSİJEN MASKELİ NEBULİZER SET (Nebulizer Set with Oxygen Mask)

Ürün Tanımı (Product Information)

Oxygen Mask Nebulizer Set is a biocompatible, non-sterile, disposable product which finishes 3ml medicine in 10 minutes and have 2 micron partical size. 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.
- * Hose: It is a 210cm 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.
- * Nebulizer Chamber: It consists of 3 parts;
 - Chamber Cover: It is polypropylene material in white color.
 - House spacer: It is polystyrene material in blue color.
 - House: It is transparent, polystyrene material. 10ml drug capacity.

Kullanım Amacı (Intended Use)

With its design suitable for facial anatomy, it provides oxygen and/or medication to the patient with a mask.

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

31309
 Tubing Set, Nebulizer

Ambalaj
Packing

Parça Adı	Adet
Oksijen Maskesi oxygen mask	1
Nebulizer Haznesi nebulizer bottle	1
Hortum tubing with connectors (iki ucuna da konnektör yapıştırılmış)	1

Biyolojik Değerlendirme
Biological Evaluation

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.

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	T20163					
Pediyatrik Pediatric	T20162		---	X	---	5 yıl 5 years
Bebek Infant	T20161					