



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

TF – 02

Yayın Tarihi

01.08.2021

Revizyon No

00

Revizyon Tarihi

NAZAL OKSİJEN KANÜLÜ (Nasal Oxygen Cannula)

Ürün Tanımı (Product Information)

Nasal Oxygen Cannula is a biocompatible, latex-free (phtalate free), non-sterile, disposable product with a 6L flowrate. It consists of the parts defined below;

- * Hose: It is a 200cm connection hose made of PVC, channeled, resistant to breakage and bending.
- * Nasal Cannula: Made of biocompatible PVC. It has a structure that does not irritate the nose and prevents the drying of the mucous membrane. The soft nasal cannula has a support that prevents rotation. For pediatric nose tip diameter 3mm, height 6mm and distance between tips are 6 mm.
- * Connector: Made of PVC, compatible with the product. There is 1 connector. It is attached to the end of the hose with adhesive.
- * Connection Intermediate End: PVC end that connects two hoses. It is attached to the hose ends with adhesive.
- * Adjustment Ring: It is a PVC ring that connects the cannula hose. It allows the cannula to be adjusted according to the patient.

Kullanım Amacı (Intended Use)

It provides oxygen to the patient by adjusting the appropriate oxygen pressure with the connection hose connected to the oxygen source.

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

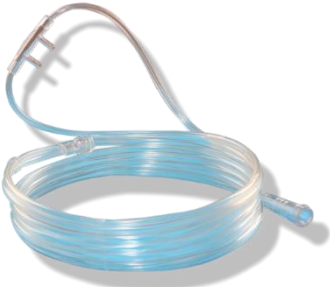
35201
Cannula, nasal, oxygen

Ambalaj
Packing

Parça Adı	Adet
Hortum - Tubing	1
Burun Kanülü - Nasal Tip	1
Konnektör - Connector	1
Ayarlama halkası- Adjusting Tip	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-2 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	T20169					
Pediyatrik Pediatric	T20171		---	X	---	5 yıl 5 years
Bebek Infant	T20172					