	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 (phthalate 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

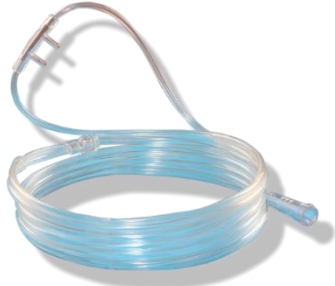
35201
 Cannula, nasal, oxygen

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		---	X	---	5 yıl 5 years
Pediyatrik Pediatric	T20171					
Bebek Infant	T20172					