CANBEY

TEKSTİL İNŞAAT VE ELEKTRONİK SAN.TİC.LTD.ŞTİ

MANUFACTURER

CANBEY TEKSTİL İNŞAAT VE ELEKTRONİK SANAYİ TİCARET LİMİTED ŞİRKETİ

İkitelli Organize Sanayi Bölgesi Mahallesi Eski Turgut Özal Caddesi No:6 B Blok No:308 Altıntaç İş Merkezi Başakşehir /İstanbul

PRODUCT DESCRIPTION

Layered and molded medical device classified in the Class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Brand Name: CANBEY **Model**: 3448
Type IIR
Device UDI-DI Number: 86829523448YZ
Product Risk Class: Class I

The Producer / the Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Producer's / the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- Government Regulation no. 2017/745/EU Medical devices establishing technical requirements for medical devices, in effective wording
- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
- Other relevant harmonized legislation
- Other relevant local, national and community standards
- For the assessment of conformity, the following documents were also applied to:
- Tests for irritation and delayed-type hypersensitivity
- Results of laboratory tests Ekoteks Testing Laboratory Bavterial filtration efficiency (Annex I)
- Results of laboratory tests Ekoteks Testing Laboratory Microbial Cleanliness (Annex I)
- Results of laboratory tests Ekoteks Testing Laboratory Differential Pressure (Annex I)
- Results of laboratory tests Ekoteks Testing Laboratory Splash Resistance Pressure (Annex I)

MARKING, LABELLING

Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied:
Type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN ISO 20417:2021 should be considered

MEASURES TO ENSURE CONFORMITY

The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

CE

Abdullah CANBEY
General Manager
2021 / İSTANBUL