

Date: Mar. 14, 2022

Product Technical Sheet

Product Description

Product: Face mask, 3-ply, latex free ear loops

Item No.: 402414

Colour: Blue

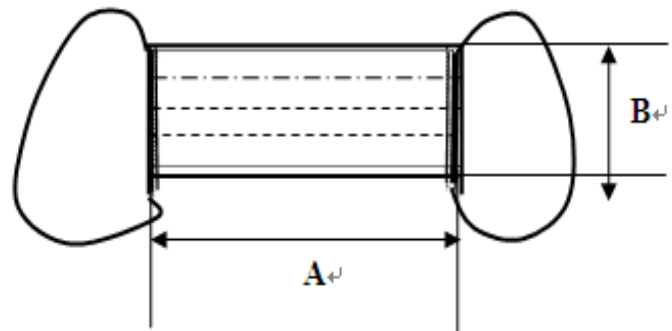
Thickness: 25g+25g+25g

Material: Polypropylene

Size: 17.5x 9.5(± 0.5)cm

Packing: 10pcs/bag, 5bags/inner box, 20boxes/ctn

Carton meas. : 52 x 42 x 34 cm



Suggested Sterilization

ETO: (pre-treatment cycle 16-72 hrs)

(gas contact – 3 hrs/850 mg)

(evaporation 48 hrs at 40°C)

Suggested Storage:

Temperature : between -5°C and 40°C

Humidity : below 80%

Sunlight : not to expose to direct sunlight

Shelf-Life : 2 years

Intended Use: Used to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements, reduce the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical.

Applicable Directive/Regulation:

Article 19, Annex II and Annex III according to Regulation (EU) 2017/745

Applicable Standards:

ISO13485:2016

ISO10993-5:2009

ISO10993-10:2010

EN14683:2019+AC:2019(TYPE II)

Risk Analysis

The raw material is approved to be safe to human health. As for the product, no hazard is foreseeable to the safety and health of user.



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Instruction for Use:

Usage :

1. Take it out from the package (box or polybag).
2. Put the elastics loop onto the ears, adjust nose bar make the mask clings to your face.

Cautions:

1. This product is for single use. Do not re-use it.
2. This product is for protection of part of body, not for overall protection.
3. This product is for hygienic protection, not for any other personal protection against potential risk.
4. This product is non-sterile. It must be sterilized before being used as sterile wear.
5. Do not wear it in the place where electrostatic prevention is requested. It is not anti-static treated.