

Date: Mar. 3, 2025

Product Technical Sheet

Product Description

Product: Face mask, 3-ply, latex free, tie back

Item No.: 403375

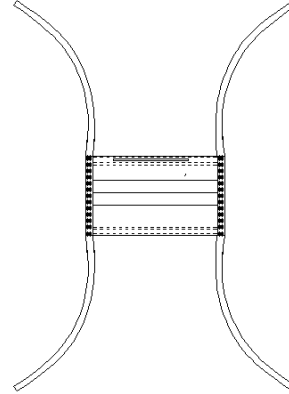
Colour: Blue

Thickness: 30g+25g+20g

Material: PP, melt blown

Size: 17.5x 9.5(±0.5)cm

Tie Length = 40cm ± 1cm



Packing: 50pcs/inner box, 20boxes/ctn

Carton meas. : 52 x 40 x 50 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 : 3 years(until LOT 4501358074 production date 2025-01-15, valid date 2028-01-14), 5 years
(from LOT 4501370782 production date 2025-02-20 valid date 2030-02-19, according to face Mask

Accelerated Aging Test Report)

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:

Medical Device Regulation (EU) 2017/745

PPE Regulation (EU) 2016/425

Applicable Standards:

ISO 13485:2016

ISO 10993-5:2009

ISO 10993-10:2010

EN 14683:2019+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.

Instruction for Use:

Usage :

1. Take the face mask out from the package (box or polybag).
2. Tie the two laces on the bottom at the back of your neck and pull tight, pull up the two laces on the top, cover the mask on your mouth and nose, tie the two laces at the back above your ears and pull tight, 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.