

Date: Jan. 18, 2021

## Product Technical Sheet

Customer: Lotus NL B.V., Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands.  
(the authorized representative in Europe)

### Product Description

Product: Face mask, 3-ply, latex free elastic loop-round-402414

Colour: Blue

Thickness: 25g+25g+25g

Material: Polypropylene

Size: 17.5x 9.5(±0.5)cm

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

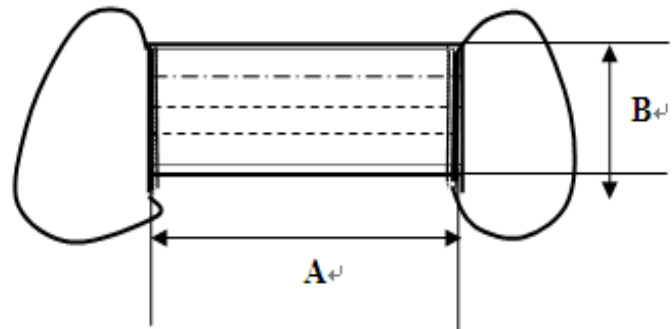
Carton meas. : 52 x 38 x 34 cm

### 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 : 5 years

**Intended Use:** It is skin friendly high-quality PP material, low breathing resistance, bacterial filtration efficiency (BFE) > 98%, nosepiece can be adjustable individually. It can be used in hospital, food industries, industry and pharmaceutical applications.

### Applicable Directive/Regulation:

Directive 93/42/EEC for medical device class I

Regulation (EU) 2016/425 for PPE cat. I

**Applicable Standards:**

ISO9001  
ISO13485  
EN14683:2019+AC:2019  
TYPE II  
EN1186

**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 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.