

Date: Mar. 3, 2025

## **Product Technical Sheet**

### **Product Description**

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

Item No.: 481661

Colour: Blue

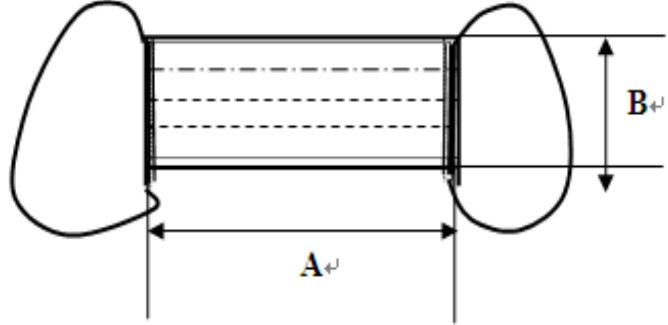
Thickness: 25g+25g+20g

Material: Polypropylene

Size: 14.5x 9.5(±0.5)cm

Packing: 50pcs/box, 2000pcs/ctn

Carton measurement: 52\*34\*36cm



### **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 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.