

Product Technical Specification Sheet

1. Product name
Surgical mask

2. Standard
EN14683:2019 Type IIR

3. Model
PLY-001

4. Product structure and composition

The Surgical Masks are Flat ear loops type, utilizing Ear Loops for wearing, and they have Nose Piece design for fitting the face mask around the nose.

The Surgical Masks are manufactured with three layers. The outer layer is made of polypropylene (PP) non-woven fabric with blue color. The middle layer is filtration function and is made of polypropylene (PP) melt-blown non-woven fabric. The inner layer contact with face is made of polypropylene (PP) non-woven fabric with white color.

The Surgical Masks are held in place over the user's mouth and nose by two elastic ear loops. The elastic ear loops are made of Polyester and Spandex.

The nose piece contained in the proposed device is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of nose piece covered with plastic polypropylene.

The shelf-life of the product is 2 years.

5. Photo

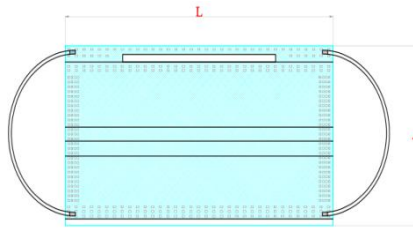


Figure1, Flat ear loops

6. Size

The surgical mask's size is

L*h:175*90±5%mm

7. Raw materials

NO.	Model	Parts name	Material	Specification Material
1.	PLY001	Face masks Inner layer	Polypropylene non-woven	25g±2g/m ² white non-woven fabric
2.		Face masks middle layer	Polypropylene melt-blown non-woven fabric	27±2g/m ² melt-blown non-woven fabric
3.		Face masks outer layer	Polypropylene non-woven	30±2g/m ² blue non-woven fabric
4.		Elastic bands	Polyester fiber & Spandex	White round elastic string

5.		Nose piece	PP strip with stainless steel inside	Width 2.5-3 mm
----	--	------------	--------------------------------------	----------------

8. Product Performance

To ensure the performance and safety of the device during clinical use, the technical specification has been established to ensure fulfillment of essential requirements. Key performance according to EN 14683:2019 is listed as follows:

Dimension	The size of the mask should meet the design requirements with an allowable tolerance of 5%
Appearance	The appearance of the mask should be smooth, without damage, stains, deformation and other obvious defects.
Nose piece	The mask should be equipped with a nose piece, which is made of flexible materials and should be no less than 8.0cm in length.
Elastic bands	The Elastic bands should be elastic and suitable, the rupture strength of the mask belt and the connection between the mask belt and the mask body should be no less than 10N.
Bacterial filtration efficiency (BFE)	$\geq 98\%$
Differential pressure	$< 60 \text{ Pa/cm}^2$
Microbial cleanliness	$\leq 30 \text{ cfu/g}$
Splash Resistance Pressure	$\geq 16.0 \text{ kPa}$

9. product warning

- Don't use if package is damaged
- If there is redness, swelling and itching after usage, please stop using it and consult your physician.
- Only for single use. Discard it after use.
- Stay away from fire.
- Do not reuse it after drying or disinfecting.
- Correctly distinguish the front and back prior to use.
- The device should be stored in a dry room with excellent ventilation and without caustic gases.
- Properly discard the used Surgical Mask according to local policy. Avoiding re-use and cross infection.
- product expiry date: 2 years