

Xiamen Flyman Technology Ltd Tongan Branch					
Product Introduction			Prepared by	BIYUAN LV	
			Checked by	XIAOAN ZHU	
			Approved by	XIAOLIN ZHENG	
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1. Produce description

1.1 Disposable Medical Face Mask is composed of mask body, nose clip, mask belt. The mask body is three-layer structure, the bottom layer and the surface layer are made of non-woven fabric, the filter layer is made of melt-blown non-woven fabric; the nose clip is made of polyethylene plastic; and the mask belt is made of elastic tape. This mask is provided in non-sterile.

According to the MDD, Annex IX, Rule 1, this Disposable Medical Face Mask is classified as Class I.

Product	Models / Specification(s)
Disposable Medical Face Mask	17.5x9.5cm, 14.5x9.5cm, 12.5x7cm

Sheet 1

1.2 Intended Use and applicable people:

Mainly used to protect patients. For clinical medical personnel to wear, covering the mouth, nose and mandible of the user, to prevent the direct transmission of pathogenic microorganisms, body fluids, particulate matter and other physical barriers. It is suitable for non-protective isolation requires medical environment, non-special purifying environment, and is not suitable for sterile environment.

1.3 The Side effect of disposable medical face mask

Allergic to product materials is forbidden.

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1.4 Main Technical Data, specifications:

Performance Requirement Type: Type IIR

Bacterial Filtration Efficiency (BFE): >98%

Breathability (Differential Pressure): <60Pa/cm²

Splash Resistance: ≥16kPa

Microbial Cleanliness: ≤30 (CFU/g)

1.4.1 Product Composition and Raw Materials:

Main Materials: 70% Nonwoven Fabric, 30% Meltdown Cloth.

Product Parts	Quality Requirements	Material	Manufacturer
Mask outer layer	Not less than 25 g/m ²	Spunbond non-woven fabric (polypropylene)	Xiamen Entrepreneur Environmental Technology
Mask inner layer	Not less than 25 g/m ²	Spunbond non-woven fabric (polypropylene)	Xiamen Entrepreneur Environmental Technology
Mask body middle layer	Not less than 25 g/m ²	Meltblown nonwoven fabric (polypropylene)	Jinjiang Xingtai Nonwoven Products Co., Ltd.
Nose clip	80mm±0.5mm	Plastic Material (Polypropylene +Iron)	Shenzhen Haosen Hardware Plastic Products Co., Ltd.
Mask band (ear-hook)	160mm±0.5mm	Polyester + spandex	Xiamen Shunyi long Weaving Co., Ltd.
self-sealing Plastic bag	13*25cm, Tolerance ±0.5%	PPE+CPP	Xiamen Minghuishun Plastic Packing Co., Ltd.

1.4.2 Main Technical Performance and Parameters:

a) Appearance

The appearance of the mask should be neat and intact, and the surface must not be damaged or stained.

b) Structure and dimensions

After wearing the mask, it should be able to cover the wearer's mouth, nose and jaw; the size should meet the requirements of the above table.

c) Nose clip

The nose mask should be equipped with a nose clip made of plastic material;

The length of the nose clip should not be less than 8.0cm.

d) Mask band

Mask bands should be easy to wear and take;

The breaking strength at the connection point between each mask band and mask body should not be less than 10N.

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e) Bacterial filtration efficiency (BFE)

The bacterial filtration efficiency of the mask should not be less than 98%.

f) Breathability (Differential Pressure): <60Pa/cm²

g) Splash Resistance (k Pa) ≥16.0

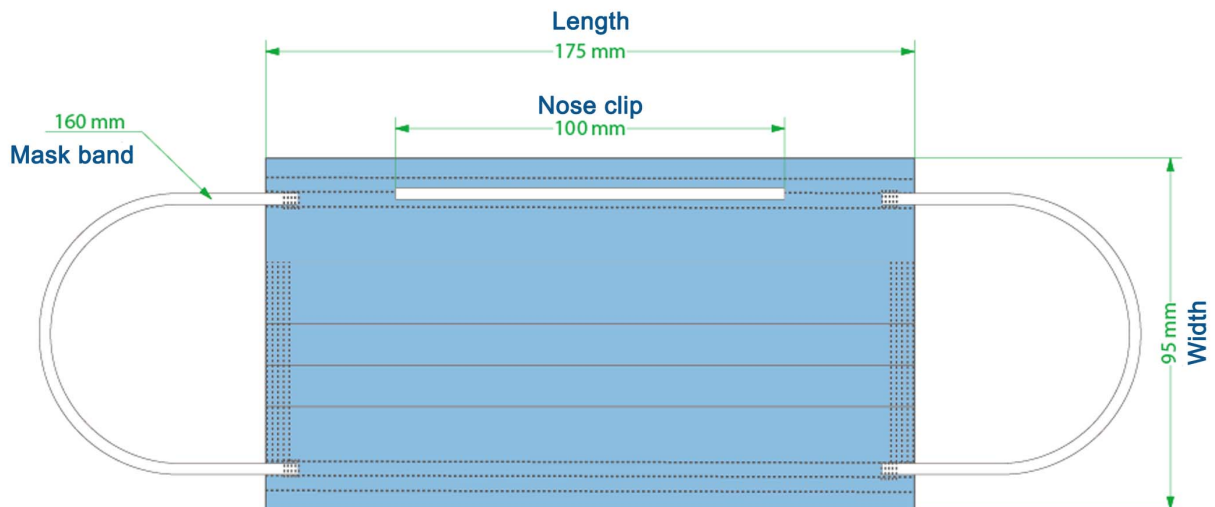
h) Microbiological indicators

Non-sterile masks should meet the requirements of the following table.

Non-sterile mask microbial index:

Total bacterial colonies CFU/g	Coliform	Pseudomonas aeruginosa	Staphylococcus aureus	Hemolytic Streptococcus	Fungus
≤30	Not detectable	Not detectable	Not detectable	Not detectable	Not detectable

1.6 Product schematic diagram



2 Operation, transportation and storage condition

Avoid sunshine and keep dry. It is recommended to store in a clean room with humidity less than 80%, no corrosive gas and good ventilation.

3 Instruction

See Annex 1.3.1 about the manuals of Disposable Medical Face Mask.