



## Package Insert



### Medical Mask

This product is a non-sterile, disposable single use surgical mask. These Surgical Masks are not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators. They are not intended to provide protection against pathogenic biological airborne particulates and are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure.

**Medical Mask** is included a table of the ASTM F2100-19 requirements for the level 1 as below:

Characteristic	Level 1 Barrier – ASTM F2100
Bacterial filtration efficiency, %	≥ 95
Differential pressure, mm H <sub>2</sub> O/cm <sup>2</sup>	<5.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥ 95
Resistance to penetration by synthetic blood, minimum mmHg	80
Flame Spread	Class 1

Medical Masks have not been FDA cleared or approved.

Medical Mask is authorized by the FDA only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

Intended Use of Product:

Medical Mask has been authorized by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) for use in healthcare settings by health care personnel (HCP) as personal protective equipment (PPE) to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the Coronavirus Disease 2019 (COVID-19) pandemic.

Surgical Masks are loose-fitting devices worn over the user's nose and mouth. Surgical masks may be effective in blocking splashes and large particle droplets; however, because of the loose fit between the surface of the surgical mask and the user's face, leakage can occur around the edge of the mask when the user inhales. Therefore, a surgical mask may not provide the user with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection. For this reason, surgical masks are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure. In such clinical conditions, a filtering facepiece respirator (such as an N95 respirator) with a tight fit is recommended to provide a more reliable level of respiratory protection against pathogenic biologic airborne particulates.

**A list of body-contacting materials including nose wire. This product is not made with natural rubber latex.**

<b>Layer</b>	<b>Material</b>	<b>Body Contact (intact skin)</b>
Inner Layer	Non-woven Polypropylene	Direct
Middle Layer	Melt Blown Polypropylene	Indirect
Outer layer	Non-woven Polypropylene	Indirect
Nose Strip	Polyethylene with Galvanized iron wire	Indirect
Ear loops	Nylon and Spandex	Direct

**instructions for donning/ doffing mask**

1. Determine which side of the mask is the top. The side of the face masks with a stiff bendable metal strip is the top.
2. Make sure the exterior side (the green colored side) of the mask is facing out away from your face.
3. Hold the mask by the ear loops and place one loop around each ear.
4. Pinch the metal strip of the mask around the bridge of the nose until it fits snugly.
5. Pull down the bottom of the mask over your chin to make sure your nose and chin are covered.
6. Remove the mask when breathing difficulties occur.
7. Hold both ear loops and gently lift and remove the mask. Avoid touching the front of the mask, as it may be contaminated. Dispose in a covered trash bin.

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**Made in PHILIPPINES**