



**Seller Information:**

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**Device Information:**

**Proprietary/Trade Name:** Phenotype 3-Ply Surgical Mask, ASTM level 3  
**Established/Generic Name:** Surgical Mask  
**Model Number:** PM-03

**Product Description:**

Phenotype surgical mask (model PM-03) is a single use, flat pleated type mask, with earloops and a nose piece for fitting the facemask around the nose. They are blue on the outside and white on the inside.

The surgical mask is manufactured with three layers. The inner and outer layers are made of spunbond polypropylene and the middle layer is made of a meltblown polypropylene filter. The layers are joined together by ultrasonic welding.

The surgical mask is held in place over the user’s mouth and nose by two elastic earloops that are welded to the facemask. No natural rubber latex materials are used for the earloop elastic. Made of nylon/spandex.

The nosepiece contained in the layers of the facemask allows the user to fit the facemask around their nose and is made of malleable carbon steel coated in polypropylene.

The mask is **Assembled in the USA**. It is a single use, disposable device and is provided non-sterile.

**Table 1: List of Body Contacting Material**

Layer	Material	Skin Contact
Inner Layer	Non-Woven Polypropylene SS Spunbond	Direct
Middle Layer	Non-Woven Polypropylene Meltblown	Indirect
Outer layers	Non-Woven Polypropylene SSS Spunbond	Indirect
Nosepiece	Polypropylene Coated Carbon Steel	Indirect
Earloops	Nylon/Spandex	Direct



**Instructions for Use:**

How to put on a face mask

1. Clean your hands with soap and water or hand sanitizer before touching the mask.
2. Remove a mask from the package and make sure there are no obvious tears or holes in either side of the mask.
3. Determine which side of the mask is the top. The side of the mask that has a stiff bendable edge is the top and is meant to mold to the shape of your nose.
4. Determine which side of the mask is the front. The colored side of the mask is usually the front and should face away from you, while the white side touches your face.
5. Hold the mask by the ear loops. Place a loop around each ear.
6. Mold or pinch the stiff edge to the shape of your nose.
7. Pull the bottom of the mask over your mouth and chin.

**Summary of FDA-Mandated Testing Data:**

Consistent with the FDA’s guidance & policy “Enforcement Policy for Face Masks and Respirators during the Coronavirus disease (COVID-19) Public Health Emergency (Revised) part V-E, May 2020,” a summary of the testing results of the ASTM F1862 Fluid Resistance Test and the 16 CFR 1610 Flammability Test are shown below. The testing was performed by SGS, an internationally recognized and certified testing company.

**Table 2: Determination of fluid resistance (ASTM Level 3 Barrier) & Flammability**

	Test Method	Minimum Acceptance Threshold	Test results
Resistance to Penetration by Synthetic Blood - ASTM Level 3 @ 160mmHg	ASTM F1862	No Fluid Penetration at 160 mmHg pressure	<b>PASS –</b> No Fluid Penetration, 32/32 samples
Flammability Class – Fabric Safe for Clothing	16 CFR part 1610	Class 1 – fabric takes ≥ 3.5s to burn	<b>PASS –</b> No Ignition, 5/5 samples

**Intended use:**

Phenotype PM-03 masks are 3-layer pleated masks that cover the user’s nose and mouth and provide a physical barrier to fluids and particulate materials and are tested for flammability as described in FDA’s guidance & policy [“Enforcement Policy for face masks and respirators during the Coronavirus disease \(COVID-19\) Public Health Emergency \(Revised\) part V-E, May 2020”](#).

Surgical masks 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 a significant risk of infection through inhalation exposure.