



Manufacturer Information:

Manufacturer Address: Phenotype Pharmaceuticals
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Device Information:

Proprietary/Trade Name: Phenotype Disposable 5-layer Surgical Mask
Established/Generic Name: Surgical Mask
Model Number: EL-05 (Earloop)

Product Description:

Phenotype’s surgical mask (model EL-05 Earloop) is a single use, 5-layer, flat folded face mask, with earloops and a nose piece for fitting the facemask around the nose.

The five layers are joined together by ultrasonic welding. Details are listed in the table below.

The face mask is held in place over the user’s nose and mouth by two elastic earloops that are welded to the facemask. No natural rubber latex materials are used for the elastic, which is made of nylon/spandex. Headstraps in place of earloops is possible upon request.

The nosepiece contained in the layers of the facemask allows the user to fit the face mask around their nose and is made of polyethylene-coated carbon steel.

The mask is a single use, disposable device and is provided non-sterile.

The 5-layer face mask is **Made in the USA** with Domestic and Imported material.

Table 1: List of Body Contacting Materials

Layer	Material	Skin Contact
Layer 1	Polypropylene Spunbond 30 GSM	Direct
Layer 2-3	Polypropylene Meltblown 27 GSM	Indirect
Layer 4	Hot Air cotton 45 GSM	Indirect
Layer 5	Polypropylene Spunbond 50 GSM	Indirect
Nosepiece	Polyethylene-Coated Carbon Steel	Indirect
Earloops	Nylon/Spandex	Direct



Instructions for Use:

How to put on a surgical mask

1. Clean your hands with soap and water or hand sanitizer before touching the mask.
2. Remove a mask from the package, unfold it 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. Hold the mask by the ear loops and place it on your face with a loop around each ear. Pull on the sides of the mask to form it against your face.
5. Make sure the mask covers your nose and wraps under your chin with the nose piece up.
6. Using both hands, bend the metal nose clip against your face to form a tight seal around the nose.
7. Perform a fit check. Place both hands over the mask. Exhale sharply to check for air leaks.

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 Eurofins Laboratory (Lancaster, Pennsylvania).

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

	Test Method	Minimum Acceptance Threshold	Test results
Resistance to Penetration by Synthetic Blood - ASTM Level 2	ASTM F1862	No Fluid Penetration at 120 mmHg pressure	PASS – No Fluid Penetration, 32/32 samples
Flammability Class – Fabric Safe for Clothing	16 CFR part 1610	Class 1 – fabric takes ≥ 3.5s to burn	PASS – No Ignition, 9/9 samples

Intended use:

Phenotype’s surgical masks (Model EL-05 Earloop) are 5-layer, flat-folded 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](#)”.

For Healthcare Professionals Only: Surgical masks are not recommended for use in clinical aerosol generating procedures and any clinical conditions where there is a significant risk of infection through inhalation exposure.