



MEDTECS (TAIWAN) CORPORATION Fact Sheet for Healthcare Personnel under the Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic

The MEDTECS (TAIWAN) CORPORATION (“Medtecs”) Surgical Face Mask is a disposable, single-use surgical mask consisting of 3-ply polypropylene materials, a nose wire, and elastic ear loops that does not contain natural rubber latex, any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents.

The product is not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators.

In addition, the Medtecs Surgical Face Mask is not intended to provide protection against pathogenic biological airborne particulates and is not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure; and

The Medtecs product has not been FDA cleared or approved.

Rather, it has been authorized by the FDA under an EUA for use in healthcare settings by HCP as 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 COVID-19 pandemic

This product is authorized 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.

Medtecs 2020.11.09

Medtecs Surgical Face Mask

ASTM LEVEL 1

Disposable surgical mask

Elastic ear loops do not contain natural rubber latex

3-PLY Polypropylene Materials

Latex free and not included any drugs or biologics

Dimensions 17.5 cm x 9.3 cm

Green or Blue, Non-Sterile and Single-Use

Composition

Direct body contact areas may include the face, mouth, nose, and ears.

Layer	Material	Body Contact (intact skin)
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 Use

Wearing Instructions:

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 (usually the 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 of the 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.

Precautions:

1. The face mask is for single-use only and should not be reused.
2. Avoid repeated folding or bending of the metal strip on top of the mask.
3. Not recommended for children under 3 or those with allergy to non-woven materials.

Medtecs 2020.11.09