



# MEDICAL GRADE DISPOSABLE SURGICAL MASK

ASTM LEVEL 1 SURGICAL MASK PER ASTM F2100-19



**Item:** 3-Ply Mask

**Description:**

Medical Grade Disposable Surgical Mask

**Material:** Non-Woven Fabric

**Colors:** Blue/White

**Size:** 3.75" x 7"

**Minimum Order Quantity:** 1 case

**Case Pack:** 2,000 each per case

Component	Composition
Fabric (3Ply)	
Outer Layer	PP Spun-bond nonwoven
Inner Layer	PP Spun-bond nonwoven
Middle Layer	PP Melt blown nonwoven filter media $\geq 95\%$
Nose Strip	PE Coated nose wire
Ear Loop	Elastic

## About Venus Group

Venus Group is a minority-owned, ISO 9001 Certified business enterprise based in CA.

Distribution centers across the U.S. including TX, FL, IL, CT, SC and CA.

Contact Us Today For More Information

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Venus Group, Inc.

Medical Grade Disposable Surgical Mask  
ASTM Level 1 Surgical Mask per ASTM F2100-19

Manufactured with pride in the USA  
SGS Test Reports Attached  
ISO9001:2015 Certificate Attached  
ASTM Level 1 Surgical Mask per ASTM F2100-19

- Flame Spread: Class 1
- Breathability: <4.0 mmH<sub>2</sub>O/cm<sup>2</sup>
- Particulate Filtration Efficiency ≥95% @0.1 micron
- Bacterial Filtration Efficiency ≥95%
- Fluid Resistance: 80 mmHg

Non-sterile, Disposable, Single use only. Discarded masks (or masks damaged or contaminated with blood/ fluids) should be treated as clinical waste and should not be discarded at random.

These surgical masks are not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators and do not eliminate exposure to or risk of contracting disease or infection. 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 significant risk of infection through inhalation exposure.

**Intended Use:**

The Venus Medical Grade Disposable Surgical Mask has been authorized by FDA under an EUA for use in healthcare settings by healthcare 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 COVID-19 pandemic.

Venus Medical Grade Disposable Surgical Masks have not been FDA cleared or approved. Venus Medical Grade Disposable Surgical Masks are 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. They are intended to be used when FDA-cleared surgical masks or FDA cleared or authorized respirators are not available. The Venus Medical Grade Disposable Surgical Mask is a loose-fitting device 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.

## Specifications

<b>Component</b>	<b>Composition</b>
Fabric (3Ply)	
Outer Layer	PP Spun-bond nonwoven
Inner Layer	PP Spun-bond nonwoven
Middle Layer	PP Melt blown nonwoven filter media $\geq 95\%$
Nose Strip	PE Coated Nose Wire
Ear Loop	Elastic



Color: blue/white

Size: 3.75" x 7"

Minimum Order Quantity: 1 case

Case Pack: 2,000 ea per case

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#surfacemasks>

# FACT SHEET FOR HEALTHCARE PERSONNEL

Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic  
August 5, 2020

Coronavirus  
Disease 2019  
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of authorized disposable, single-use surgical masks (hereafter referred to as “authorized surgical masks”) during the COVID-19 pandemic.

Certain surgical masks are authorized for emergency use by healthcare personnel (HCP) in healthcare settings 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 COVID-19 pandemic. This Fact Sheet is specific to surgical masks that were authorized by the United States Food and Drug Administration (FDA) under an emergency use authorization (EUA).

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**Healthcare personnel should adhere to Standard and Transmission-based Precautions when caring for patients with SARS-CoV-2 infection per CDC guidelines.**

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## What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the Centers for Disease Control and Prevention (CDC) webpage for the most up to date information.

## What do I need to know about the emergency use of authorized surgical masks?

- Authorized surgical masks meet the fluid barrier, flammability, and particulate filtration efficiency performance requirements set forth in the EUA and do not pose significant risks concerning breathability and biocompatibility.
- Authorized surgical masks may be effective in blocking respiratory droplets and large particles.
- Authorized surgical masks do not include drugs, biologics, nanoparticles or antimicrobial/antiviral agents and are not FDA-cleared.
- HCP should review the authorized surgical mask labeling prior to use and follow the instructions for use.

Use appropriate PPE when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC’s webpage, *Information for Healthcare Professionals* (see links provided in “Where can I go for updates and more information” section).

## When is it not appropriate to use an authorized surgical mask?

- Authorized surgical masks are not intended to replace the need for FDA-cleared surgical masks.
- Surgical masks may not provide the user a reliable level of protection from inhaling smaller airborne particles and are not personal respiratory protective devices. They are not intended to replace the need for FDA-cleared or authorized respirators.
- Because of the loose fit between the surface of the surgical mask and the user’s face, surgical masks used by HCP are not considered respiratory protection against pathogenic biological airborne particulates.
- Surgical masks are not recommended for use in aerosol generating procedures and any clinical

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**Report Adverse events**, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

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conditions where there is significant risk of infection through inhalation exposure. Under those conditions, a filtering facepiece respirator (such as an N95 respirator) with a tight fit should be used to provide a more reliable level of respiratory protection.

## What are the known and potential benefits and risks of authorized surgical masks?

Potential benefits of authorized surgical masks:

- Decreases risk of transmitting the SARS-CoV-2 virus to the wearer, other HCP, or patients
- Helps prevent HCP exposure to the spread of infection or illness

Potential risks of authorized surgical masks:

- Inadequate barrier protection leading to spread of infection or illness
- Loose-fitting contributing to inadequate respiratory protection against pathogenic biological airborne particulates
- Adverse reaction to device materials
- Flammable in the presence of high intensity heat sources or flammable gas
- Difficulty breathing

## What is an EUA?

The FDA has made surgical masks available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

This product has been authorized by FDA under an EUA for use by HCP as PPE in healthcare settings 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. An authorized surgical mask made available under an EUA has not undergone the same type of review as an FDA-approved or cleared

device. This product has not been FDA-cleared or approved. However, in the absence of an FDA-approved or cleared alternative and based on the totality of scientific evidence, it is reasonable to believe the authorized surgical mask may be effective for the authorized use. 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, unless the authorization is terminated or revoked sooner.

An FDA approved or cleared device should be used instead of the authorized surgical mask under EUA, when available.

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## Where can I go for updates and more information?

### **CDC webpages:**

**General:** <https://www.cdc.gov/COVID19>

**Healthcare Professionals:**

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

**Infection Prevention and Control Recommendations in Healthcare Settings:**

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

**Infection Control:** <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

### **FDA webpages:**

**General:** [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)

**EUAs:** <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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