



Premier Guard USA Fact Sheet for Healthcare Personnel under the Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic

The Premier Guard USA (“PGUSA”) 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 PGUSA 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 PGUSA 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.

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REF 20-1002-SFM3

Premier Guard USA Surgical Face Mask

ASTM LEVEL 3

Disposable surgical mask

Elastic ear loops do not contain natural rubber latex

3-PLY Polypropylene Materials

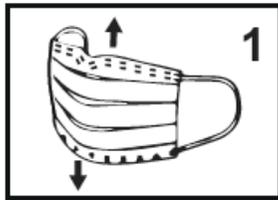
Dimensions 17.5 cm x 9.5 cm

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 laminated double sided 24-gauge soft annealed carbon steel wire tie	Indirect
Elastic ear loops	Polyester/Spandex	Direct

Instructions for Use:



1. Spread out the mask and pull it apart in the up and down direction



2. Fix the nose clip in the shape of nose



3. Pull the mask to the chin

Replace mask after a single use or when wet or soiled. Do not reuse.

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Questions:
888-706-1231 (9am-5pm CST)
www.premierguardusa.com



Do Not Reuse



Does Not
Contain
Natural Rubber
Latex



Do Not Use
if Package is
Damaged



Protect from
sunlight



Protect from
moisture

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