

# Surgical Mask 20190019



## KEY FEATURES

The 3 layer design provides BFE and PFE > 98%  
White color available, one size fits all (17.5 x 9.5cm)  
Adjustable nose clip significantly reduces air penetration  
Ultrasonically welded earloops stay firmly attached  
FDA approval, 510(k) Number: K201517

## MATERIAL COMPOSITION

Outer and inner layers – spunbond nonwoven polypropylene  
Filter – meltblown nonwoven polypropylene  
Straps – polyester elastic Cord  
Nose clip – polypropylene  
This mask contains no components made from natural rubber latex  
Approximate weight of product: 3.0 grams / 0.10 oz

## INTENDED USAGE

The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.  
The mask is authorized for distribution under FDA enforcement discretion during the COVID-19 outbreak unless the authorization is terminated or revoked sooner.

## DO NOT USE FOR

The face mask is not a respirator and is not designed to replace N95  
This mask is not for a place where the infection risk level through inhalation exposure is high

## TIME USE LIMITATION

Replace the mask when it becomes dirty, damaged, or difficult to breathe through

## TESTING AND STANDARDS

FDA 510(k): K201517

ASTM F2100 Level 2 (Report from Nelson Lab)

TEST	ASTM F2100 Level 2	Typical Value
Bacterial Filtration Efficiency, %	≥98	99
Differential Pressure, mm H <sub>2</sub> O/cm <sup>2</sup>	< 6.0 (59 Pa/cm <sup>2</sup> )	3.2 (31.1 Pa/cm <sup>2</sup> )
Particulate Filtration Efficiency 0.1 Micron, %	≥98	99
Synthetic Blood Resistance mmHg	120 (16.0 kPa)	120 (16.0 kPa)
Flame Resistance	Class 1	Pass

## SHELF LIFE AND STORAGE

2 years from the date of manufacture  
Use by date on box in MM/YYYY format  
Store masks in the original packaging, away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals  
Store in temperatures between -4°F (-20°C) and +86°F (+30°C) and not exceeding 80% humidity

## Warnings

The mask is not intended for reuse and shall be discarded after each procedure.  
Check your mask's production date. Masks expire two years after the production date, after which they may not provide full protection. Before use, the wearer must read and understand the user instructions provided in the product packaging.  
Not recommended for children under 3.

## ORDERING INFORMATION

DESCRIPTION	Case Size	Case Weight	Masks/Box	Boxes/Case	Masks/Case
Surgical Mask	52 x 47 x 34cm	10.6kg	50	40	2000

