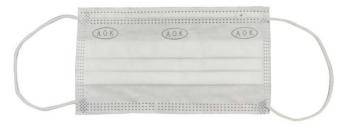
Surgical Mask 20190019



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.

DO NOT USE FOR

The face mask is not a respirator and is not designed to replace N95

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 H2O/cm2	< 6.0 (59 Pa/cm²)	3.2 (31.1 Pa/cm²)
Particulate Filtration Efficiency 0.1 Micron,%	≥98	99
Synthetic Blood Resitance 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 the 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