

Face Mask

Pending FDA Approval



Face Mask

FDA Approved



N95 Respirator



Testing and Approval	Currently not FDA Approved. Designed to FDA standards.	Cleared by the U.S. Food and Drug Administration (FDA)	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84
Filtration	>98% filtration efficiency Lab tested in Taiwan Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection.	>98% filtration efficiency Tested by FDA Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection.	Filters out at least 95% of airborne particles including large and small particles.
Intended Use and Purpose	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions. *We advise using these masks in lower contact situations until they are officially FDA approved.	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols).
Face Seal Fit	Loose-fitting	Loose-fitting	Tight-fitting
Fit Testing Requirement	No	No	Yes
User Seal Check Requirement	No	No	Yes. Required each time the respirator is donned (put on).
Leakage	Leakage occurs around the edge of the mask when user inhales.	Leakage occurs around the edge of the mask when user inhales.	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales.
Use Limitations	Disposable. Discard after each patient encounter.	Disposable. Discard after each patient encounter.	Ideally should be discarded after each patient encounter and after aerosolgenerating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.