

# COMPARISON GUIDE SURGICAL MASKS AND N95 RESPIRATORS



**Surgical Mask**



**N95 Respirator**

Approval and Regulations	Cleared by the U.S. Food and Drug Administration (FDA) and regulated under 21 CFR 878.4040.	Regulated by the FDA, CDC NIOSH, OSHA. Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84.
Intended Purpose	Fluid resistant. Reduces wearer’s exposure to and provides 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). Designed to protect both the patient and healthcare professional from the transfer of microorganisms, bodily fluids and particulate material at an N95 filtration level per 42 CFR 84.181.
Use Limitations	Disposable. Not intended to be used more than once and should be discarded if damaged, soiled or if breathing through the mask becomes difficult.	Ideally should be discarded after each patient or customer encounter. It should also be discarded when it becomes damaged or deformed; no longer forms and effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult, or it becomes contaminated with any fluids from patients or customers.
Filtration	Not considered respiratory protection. Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles.	Is considered respiratory protection. Filters out at least 95% of airborne particles including large and small particles.
Air Leakage	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.
Fit Testing Requirement	Not required	Yes, per OSHA standard 1910.134 App A.
User Seal Check Requirement	Not required	Yes. Required each time the respirator is put on, known as donning.

Sources:

- Centers for Disease Control & Prevention, "Understanding the Difference, Surgical Mask, N95 Respirator", <https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf> (Retrieved May 12, 2021)
- USFDA, "N95 Respirators, Surgical Masks, and Face Masks," <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks> (Retrieved May 12, 2021)
- USFDA, "Memorandum of Understanding Between the Food & Drug Administration *et al*," <https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006> (Retrieved May 12, 2021)