

<https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks>



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N95 Respirators, Surgical Masks, and Face Masks

N95 respirators and surgical masks are examples of personal protective equipment that are used to protect the wearer from airborne particles and from liquid contaminating the face. The Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) also regulate N95 respirators.

It is important to recognize that the optimal way to prevent airborne transmission is to use a combination of interventions from across the hierarchy of controls, not just PPE alone.

COVID-19 Resources on Respirators and Masks

[Face Masks, Including Surgical Masks, and Respirators for COVID-19](#): Answers to frequently asked questions, with information on using masks and respirators, shortages, Emergency Use Authorizations (EUAs), manufacturing, and importing masks and respirators

For health care providers and facilities:

- [Considerations for Selecting Respirators for Your Health Care Facility](#)
- [Surgical Mask and Gown Conservation Strategies - Letter to Health Care Providers](#)
- [Wear Face Masks with No Metal During MRI Exams: FDA Safety Communication](#)

For industry:

- [Manufacturing and Distributing Respirators for Health Care Use in the United States](#)

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CDC Recommendations for the General Public

CDC recommends that people wear [masks in public settings](#), at events and gatherings, and anywhere they will be around other people. Effective February 2, 2021, [CDC issued an order](#) requiring **masks** on planes, buses, trains, and other forms of public transportation traveling into, within, or out of the United States and in U.S. transportation hubs such as airports and stations.

Surgical Masks

A surgical mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. Surgical masks are regulated under 21 CFR 878.4040. Surgical masks are not to be shared and may be labeled as surgical, isolation, dental, or medical procedure masks. They may come with or without a face shield. These are often referred to as face masks, although not all face masks are regulated as surgical masks.

Surgical masks are made in different thicknesses and with different ability to protect you from contact with liquids. These properties may also affect how easily you can breathe through the face mask and how well the surgical mask protects you.

If worn properly, a surgical mask is meant to help block large-particle droplets, splashes, sprays, or splatter that may contain germs (viruses and bacteria), keeping it from reaching your mouth and nose. Surgical masks may also help reduce exposure of your saliva and respiratory secretions to others.

While a surgical mask may be effective in blocking splashes and large-particle droplets, a face mask, by design, does not filter or block very small particles in the air that may be transmitted by coughs, sneezes, or certain medical procedures. Surgical masks also do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the mask and your face.

Surgical masks are not intended to be used more than once. If your mask is damaged or soiled, or if breathing through the mask becomes difficult, you should remove the face mask, discard it safely, and replace it with a new one. To safely discard your mask, place it in a plastic bag and put it in the trash. Wash your hands after handling the used mask.

N95 Respirators

An **N95 respirator** is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. Note that the edges of the respirator are designed to form a seal around the nose and mouth. Surgical N95 Respirators are commonly used in healthcare settings and are a subset of N95 Filtering Facepiece Respirators (FFRs), often referred to as N95s.

Comparing Surgical Masks and Surgical N95 Respirators

The FDA regulates surgical masks and surgical N95 respirators differently based on their intended use.



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General N95 Respirator Precautions

- People with chronic respiratory, cardiac, or other medical conditions that make breathing difficult should check with their health care provider before using an N95 respirator because the N95 respirator can make it more difficult for the wearer to breathe.
- Some models have exhalation valves that can make breathing out easier and help reduce heat build-up. Note that N95 respirators with exhalation valves should not be used when sterile conditions are needed.
- **All FDA-cleared N95 respirators are labeled as "single-use," disposable devices.** If your respirator is damaged or soiled, or if breathing becomes difficult, you should remove the respirator, discard it properly, and replace it with a new one. To safely discard your N95 respirator, place it in a plastic bag and put it in the trash. Wash your hands after handling the used respirator.
- **N95 respirators are not designed for children or people with facial hair. Because a proper fit cannot be achieved on children and people with facial hair, the N95 respirator may not provide full protection.**

N95 Respirators in Industrial and Health Care Settings

Most N95 respirators are manufactured for use in construction and other industrial type jobs that expose workers to dust and small particles. They are regulated by the National Personal Protective Technology Laboratory (NPPTL) in the National Institute for Occupational Safety and Health (NIOSH), which is part of the Centers for Disease Control and Prevention (CDC).

However, some N95 respirators are intended for use in a health care setting. Specifically, single-use, disposable respiratory protective devices used and worn by health care personnel during procedures to protect both the patient and health care personnel from the transfer of microorganisms, body fluids, and particulate material. These surgical N95 respirators are class II devices regulated by the FDA, under 21 CFR 878.4040, and CDC NIOSH under 42 CFR Part 84.

N95s respirators regulated under product code MSH are class II medical devices exempt from 510(k) premarket notification, unless:

- The respirator is intended to prevent specific diseases or infections, or
- The respirator is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or
- The respirator contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms).

The FDA has a [Memorandum of Understanding \(MOU\)](#) with CDC NIOSH which outlines the framework for coordination and collaboration between the FDA and NIOSH for regulation of this subset of N95 respirators.

For additional differences between surgical masks and N95 respirators, please see [CDC's infographic](#).