

COVID-19 Frequently Asked Questions regarding use of N95 respirators, surgical masks and other respirators complying with international standards (e.g., KN95 respirators)

- **What is an N95 respirator?**

An N95 respirator (sometimes referred to as “N95 mask”) is a respiratory protection device designed to achieve a very close facial fit and very efficient filtration of airborne particles. The 'N95' designation means that when subjected to specific testing, the respirator **filters out at least 95 percent of very small (>0.3 micron) test particles**; the “N” refers to “non-oil” particles. N95 respirators are certified by the National Institute for Occupational Safety and Health (NIOSH), which is a research unit within the Centers for Disease Control and Prevention. N95 respirators worn by healthcare personnel during clinical procedures are meant to protect both the patient and health care professional from pathogenic microorganisms, body fluids, and particulate matter.

- **What is a surgical mask?**

A surgical mask is a loose-fitting device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. A surgical mask can help block droplets of the wearer’s saliva and respiratory secretions preventing the spread of viral particles. Surgical masks can also protect the wearer by preventing **large-particle droplets**, splashes, sprays, or splatter that may contain pathogens (viruses and bacteria), from reaching the wearer’s mouth and nose [1].

- **What is the difference between an N95 respirator and surgical mask?**

The intended use and purpose of a surgical mask is to provide the wearer protection against large droplets, splashes, or sprays of bodily fluids. A surgical mask can also prevent the wearer from spreading their own respiratory secretion to others. **Surgical masks DO NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles** and are not certified as respiratory protection. An N95 respirator reduces the wearer’s exposure to particles, including small particle aerosols and large droplets (only non-oil) aerosols. **N95 respirators filter out at least 95% of airborne particles including large and small particles** and are intended to be used by medical professionals performing clinical procedures [2].

- **Is the use of other respirators equivalent to the NIOSH approved N95– such as “KN95” respirators– appropriate during the COVID-19 pandemic?**

On April 3, 2020, in response to continued N95 respirator shortages, the **FDA issued a new Emergency Use Authorization (EUA)** for non-NIOSH-approved respirators made in China, which makes and certifies KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic. The web page link provided below is the complete Emergency Use Authorization by FDA: <https://www.fda.gov/media/136664/download>

For additional information about the **FDA EUA for non-NIOSH approved respirators**, please visit the following web page: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/non-niosh-approved-respirator-eua-faq>

- **What is a KN95 respirator?**

KN95 refers to the regulatory standard for filtering face piece respirators certified in China. The standard requires a design to form a seal with the face and use against most non-oily particulates with a filtration efficiency of 94-95%. The requirement for a KN95 certification is almost identical to the United States’ NIOSH N95 certification procedure. Authentic KN95 respirators provide equivalent protection of an N95 respirator.

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- **Are all KN95 masks available on the market authentic?**

Some brands of KN95 may not be authentic.

For example: Occupational Safety Team at Columbia EH&S has tested the fit factor of 3M KN95 respirator samples and has found that a desirable fit factor is achieved when a **3M KN95** is used **in combination with a surgical mask on top**. *Healthcare workers may use a combination of a KN95 respirator and a surgical mask for protection from the transfer of microorganisms, bodily fluid and particulate matter.* **Proper seal check** is essential and must be performed after donning the respirator and before entering a hazardous area, as well as, each time the fit is believed to have loosened.

The Occupational Safety Team has also tested another brand of KN95-labelled respirator that was NOT found to create a safe, tight seal around the wearer's mouth and nose.

The web page linked below provides a table of **NIOSH-approved N95 respirators**, listed alphabetically by manufacturer. To skip to a particular brand, select a manufacturer by clicking on the first letter of their name on the index. https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1.html

The web page linked below provides a table of **FDA authorized imported, non-NIOSH Approved Respirators** Manufactured in China which is updated on a regular basis. <https://www.fda.gov/media/136663/download>

- **How do I detect a counterfeit respirator?**

Counterfeit respirators bearing the NIOSH name or logo do appear in the marketplace. They are advertised as NIOSH-approved and often sold at low prices. An easy way to verify is to check for the presence of NIOSH approval **TC number** (TC-84A-XXXX) on the respirator's packaging, the user instructions, or the product itself. If the TC number is not present, it is not NIOSH-approved [3]. The following web page provides examples of counterfeit products that are not NIOSH approved:

<https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html>

- **Is the donning procedure for KN95 masks different than N95?**

The donning procedure may vary for each manufacturer. However, a **proper seal checking procedure** must be performed by the user at the time of donning a KN95. If a proper seal is not achieved, a different sized mask of an N95 must be used instead of a KN95. The CDC guidelines on how to properly put on and take off a disposable respirator are available here: <https://www.cdc.gov/niosh/docs/2010-133/pdfs/2010-133.pdf>

References:

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

[2] <https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf>

[3] <https://www.cdc.gov/niosh/docs/2013-138/pdfs/2013-138.pdf?id=10.26616/NIOSH PUB2013138>