

Kimtech™ N95 Pouch Respirator Frequently Asked Questions

Updated 3/8/21

► Product Positioning:

Q: Why is this product not for use in the healthcare market or by healthcare personnel?

A: Our NIOSH-approved non-surgical Kimtech™ N95 pouch-style respirator has been specifically designed for non-medical use to help alleviate supply shortages within the industrial, cleanroom and laboratory segments. It has not been cleared by the Food and Drug Administration (FDA) as a medical device. It is therefore not for use in the healthcare market or by healthcare personnel.

Q: Why does your packaging say “Not for Medical Use”? Does this mean I am not protected?

A: It may be helpful to understand the difference between surgical and nonsurgical respirators:

- Surgical N95 respirators are both 1) approved by NIOSH as an N95 respirator and 2) also cleared by the FDA as a surgical mask. These are classified as medical devices by the FDA and are designed to be worn by healthcare professionals during medical procedures.
- Non-surgical N95 respirators are approved by NIOSH only. They are not approved by the FDA and are not classified as medical devices.

Given the identical N95 rating, both surgical N95 respirators and non-surgical N95 respirators meet minimum filtration requirements of 95%. Our NIOSH-approved non-surgical Kimtech™ N95 pouch-style respirator has been specifically designed for non-medical use to help alleviate supply shortages within the industrial, cleanroom and laboratory segments. It has not been cleared by the FDA as a medical device. It is therefore not for medical use.



Q: Has this respirator been tested against COVID-19?

A: This N95 respirator passes all relevant NIOSH testing protocols. However, please note that NIOSH approval protocols do not include specific tests for respiratory diseases. Thus, this product has not been tested against COVID-19 or other respiratory diseases. To date and to the best of our knowledge, no other competitor has tested their N95 respirator against COVID-19 either.

Q: Is this product listed on the Emergency Use Authorization (EUA) issued by the FDA?

A: Yes, as a NIOSH-Approved N95 respirator, the Kimtech™ N95 Pouch Respirator is covered by the EUA issued by the FDA on March 28, 2020.

Q: What is the difference between the Non-Surgical N95 respirator and a Surgical N95 respirator?

A: Surgical N95 respirators have additional required features such as fluid protection resistance for splashes and sprays. While these added features are important in healthcare settings, they are not necessary in the industrial and scientific segments served by Kimberly-Clark Professional.

Additionally, the [CDC recommends](#) surgical N95s be worn only by healthcare personnel who need protection from both airborne and fluid hazards. These respirators are not used or needed outside of healthcare settings.

› Authenticity:

Q: There is a lot of fraud in the N95 marketplace. How do I ensure that your product is genuine?

A: As part of the NIOSH approval, it is required that every respirator is printed with specific information. This includes manufacturer, "NIOSH", the TC Approval Number, Filter Classification, Model Number and Lot Number. If you have any concerns about the authenticity of your Kimberly-Clark product, please contact KCPInfo@kcc.com

Additionally, customers can search the TC Approval Number on the [NIOSH Certified Equipment List \(CEL\)](#) or the [NIOSH Trusted-Source](#) page to determine if the respirator has been approved by NIOSH. NIOSH-approved FFRs will always have one of the following designations: N95, N99, N100, R95, R99, R100, P95, P99, P100.

Furthermore, the CDC maintains a list of counterfeit respirators [here](#) which buyers can review as well for additional peace of mind.

› Country of Origin:

Q: Where is this product manufactured?

A: This product is proudly made in the USA. Additionally, all ingredients used in manufacturing are also sourced from within the USA.

› Product Details:

Q: Are these respirators individually packaged?

A: These respirators are not individually packaged and come in a bulk bag of 50 respirators per bag.

Q: How many layers do these respirators have?

A: This product is made of 4 layers of materials. The outer layer provides strength and structure. The middle two layers provide filtration. The inner layer provides structure and is soft against the skin.

Q: How often should I change out these respirators?

A: These are disposable single-use respirators. The length of wear depends on many conditions and should be evaluated by the employer as part of their overall workplace respiratory protection program.

Q: Is the product electrostatic?

A: Yes, the nonwoven filtration layers are electrostatically charged.

Q: I have not seen many N95 respirators that look like this one? Why is it designed this way?

A: This style of respirator is known as a horizontal flat-fold respirator. The pouch respirator is designed to provide a larger breathing chamber which adds to the wearer's comfort. Unlike cup-shaped respirators or vertical flat fold respirators, the extra space provides more room for warm air to dissipate.

Q: The headbands are different than what I am typically used to on a N95. Do these provide the same seal?

A: The headbands on the Kimtech™ N95 Pouch Respirator are made of Kimberly-Clark patented material and are engineered specifically for their softness and strength. Given the unique material and its properties, it may feel different from a touch and feel standpoint, however it provides the needed amount of pressure and tension to generate a tight seal.

Q: Do these products have a shelf life or expiration date?

A: Yes, currently these products have an expiration date/use by date of 1 year from date of manufacture.

► Competitive Product:

Q: KN95's are now being sold in North America. How are N95 respirators different from KN95's?

A: When the pandemic crisis started, FDA and the Occupational Safety and Health Administration (OSHA) set forth interim guidance (Emergency Use Authorization or EUA) for alternative types of respiratory protection, including KN95s, that could be used in place of a NIOSH N95 respirator if NIOSH products could not be sourced due to supply shortages in the industrial market (as N95 sourcing became a priority for healthcare settings). All U.S.-based workplaces are required to place a good faith effort in acquiring NIOSH approved respirators. Alternatives are allowed, on an interim basis, due to shortages but all efforts to comply with the OSHA respiratory protection program 1910.134 requirements should be made.

Most of the products from other standards, including KN95s, have an ear loop design. NIOSH-approved N95s typically have headbands. Furthermore, limited assessment of ear loop designs indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

You can simply look at the assessment NIOSH has made on many International respirators as well as check if a respirator is on the counterfeit list published by NIOSH at the below link:

[International Assessment Results | NPPTL | NIOSH | CDC](#)

Furthermore, NIOSH maintains a list of counterfeit respirators at the link below which buyers can review as well for additional peace of mind

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

► Fit

Q: Does this product require fit testing?

A: OSHA (29 CFR 1910.134) Respiratory Protection standard requires employers to establish and implement a written respiratory program with several components, one of which is fit testing to ensure proper seal. This is true for both surgical and non-surgical N95s. The CDC offers an FAQ on fit testing at the link below:

[DHHS \(NIOSH\) Publication No. 2018-129, Filtering out Confusion: Frequently Asked Questions about Respiratory Protection, Fit Testing \(cdc.gov\)](#)

Q: How do you adjust to fit a small face?

A: Every person has a unique head shape and size. Every respirator comes with an adjustable nosepiece which allows the wearer to adjust the respirator to their face. When donning the respirator, it is important to make adjustments so that a proper seal can be achieved. If you are unable to get a proper seal with this respirator after adjustments, you may need to seek a secondary respirator option. Also, Kimberly-Clark is planning to offer a "Small Size" respirator in Q2 2021.

See video for how to properly wear the respirator [here](#)