KLEENGUARD™

KleenGuard™ N95 Particulate Respirator: Pouch Style

FREQUENTLY ASKED QUESTIONS

Updated 7/1/21

Q: What is an Emergency Use Authorization (EUA) and which specific EUA are we referring to here?

A: Emergency Use Authorization (EUA) authority allows the US FDA to help strengthen the nation's public health protections against chemical, biological, radiological and nuclear (CBRN) threats, including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies. The US FDA has issued several EUAs related to the COVID-19 pandemic, including three respirator PPE-focused EUAs.

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas

Q: Why does this apply to KleenGuard™ N95 Particulate Respirator (53899/54065) and not to the Kimtech™ N95 Pouch Respirator (53538/54066)?

A: In mid-2020, KCP decided to re-enter the respiratory protection business to respond to supply shortages in industrial and scientific channels, and in the interest of speed, the decision was made to leverage the Kimtech™ brand for its inaugural offering given previously held NIOSH approvals under that brand. KleenGuard™ remains KCP's mainline brand for the broader industrial segment and is consistent with other product categories across gloves, apparel and eyewear. To encourage migration to the mainline brand, KCP has decided to leverage the EUA to temporarily allow KleenGuard™ sales in healthcare.

Q: Why has KCP changed its position now on leveraging the EUA?

A: Two main reasons: firstly, to encourage migration to its mainline safety and PPE brand, KCP has decided to leverage the EUA to temporarily allow KleenGuard™ sales into healthcare. Secondly, we have continued to monitor the fluctuating supply/demand balance arising from the volatile COVID-19 conditions while building our domestic manufacturing footprint on N95 respirators. We can now meet the demand for industrial N95 respirators outside our core industrial and scientific segments with a high degree of confidence and are thus changing our position accordingly.

Q: If my channel partner is pursuing end-user demand in the Healthcare segment, which SKU can we offer to meet that need?

A: Per the direction in this document, we can only leverage the KleenGuard™ N95 Particulate Respirator (53899/54065) to meet end-user demand in the Healthcare market, while the EUA remains in effect.

Q: Can we now sell to emergency service personnel and first responders (police, fire, etc.?)

A: Yes. Per the direction in this document, we can only sell the KleenGuard™ N95 Particulate Respirator (53899/54065) to emergency personnel and first responders while the EUA remains in effect.

Q: Will KCP accept returns on N95 Respirators?

A: No, N95 respirators which have been sold have been under the no-returns policy that have been in effect since last year. Additionally, given the regulated nature of these products, KCP cannot accept returns on N95 respirators.

Q: The KleenGuard™ product says "Not for Medical Use" on the box, does that prohibit me from selling it into the Healthcare market or healthcare personnel?

A: No. The "Not for Medical Use" disclaimer on-pack is required by the NIOSH and FDA to denote that the KleenGuard™ N95 Particulate Respirator is not a dually approved NIOSH and FDA-approved Surgical N95 and thus, is not designed for use by the healthcare market or healthcare personnel. However, while the EUA remains in effect — it can be used in healthcare applications as per the terms outlined in the EUA.

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Q: Does that mean the KleenGuard™ N95 can now be used for surgical applications?

A: The KleenGuard™ N95 Particulate Respirator is a standard NIOSH-approved N95 respirator and is not dually cleared by the FDA or NIOSH as a surgical N95 respirator. Employers should make their determinations for applications according to OSHA, FDA and CDC guidelines and guidance on usage of filtering facepieces in surgical settings.

Q: Does that mean we can now claim that the KleenGuard™ N95 Particulate Respirator can protect against COVID-19?

A: No. The KleenGuard™ N95 Particulate Respirator is designed to provide protection against the risks posed by airborne particulates and contaminants and is approved by NIOSH to provide a filtration efficiency of at least 95% for 0.3 micron particles. While the KleenGuard™ N95 passes all relevant NIOSH testing protocols, such protocols do not include specific tests for respiratory diseases, including COVID-19. Thus, we cannot make the claim that the KleenGuard™ N95 Particulate Respirator can protect against COVID-19. To the best of our knowledge, no other manufacturer has a respirator that claims to protect against COVID-19.

Q: When the EUA ends — will KCP pursue the NIOSH/FDA clearance for surgical healthcare applications for first responders and EVS in long-term care?

A: No. Presently, KCP does not plan to pursue FDA clearance for a surgical N95 respirator. Thus, upon expiration for the EUA, the KleenGuard™ N95 Particulate Respirator will no longer be cleared for sale for the Healthcare market or healthcare personnel.

References:

- FDA EUA being referred to within this document: NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency
- EUA Clarification Letter on Respirators
- CDC Guidance on N95 Respirators

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