California Dental Association
1201 K Street, Sacramento, CA 95814
800.232.7645 | cda.org

N95 Respirators: Equivalent Respirators and Counterfeits

The U.S. Food and Drug Administration issued emergency use authorizations (EUAs) to address a critical shortage of N95 surgical respirators (also known as disposable filtering facepiece respirators). The FDA regards the respirators that have been issued EUAs to be suitable alternatives for personal respiratory protection. The EUAs issued are for:

1. Use of NIOSH-approved air purifying respirators (typically, a respirator must have additional clearance from the FDA to be used in a healthcare setting). These include elastomerics half- and full-facepiece respirators, powered air-purifying respirators and expired respirators. According to the CDC, "NIOSH-certified reusable elastomeric particulate respirators provide at least the same level of protection as N95 FFRs, and some types of elastomeric respirators can offer higher assigned protection factors than N95 FFRs." For more information on these respirators see:
    a. CDC, Elastomeric Respirators: Conventional, Contingency and Crisis Strategies.
    b. Bach, Michael PhD, RN. "Understanding respiratory protection options in healthcare: The overlooked elastomeric," NIOSH Science Blog, July 6, 2017.
    c. NIOSH Approved Particulate Filtering Facepiece Respirators (types and manufacturers listed)
2. Use of imported non-NIOSH-approved disposable filtering facepiece respirators. Most of these respirators are manufactured by 3M in the countries of Japan, South Korea, United Kingdom, Singapore, and Turkey, and have different respirator model numbers (list of authorized respirators).
3. Use of non-NIOSH-approved disposable filtering facepiece respirators manufactured in China. There are several different model numbers, including the KN95 (list of authorized respirators updated May 7, 2020); list of models no longer authorized)

FAQs on these EUAs are available on the FDA website which is updated regularly. The EUAs are valid until the end of the national public health emergency. NIOSH recently announced that in addition to revising eligibility criteria and removing previously authorized respirators, the FDA says it will increase screening of imported respirators, detain shipments of products that NIOSH has listed on its website as not meeting performance criteria and will also begin sampling respirators for further NIOSH testing, to verify product filtration efficiency.

Counterfeit products

Dentists should also be on the lookout for counterfeit respirators. CDC NIOSH has published on its website multiple examples of counterfeit respirators. Some of the signs that a respirator may be counterfeit are:

- No markings at all on the filtering facepiece respirator
- No approval (TC) number on filtering facepiece respirator or headband
- No NIOSH markings
- NIOSH spelled incorrectly
- Presence of decorative fabric or other decorative add-ons (e.g., sequins)

Related publications:

FDA revises emergency use authorization for certain non-NIOSH approved respirators
Be wary of counterfeit products marketed to dentists during the COVID-19 pandemic