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SELECTING NIOSH-APPROVED OR IMPORTED NON-NIOSH-APPROVED FILTERING FACEPIECE RESPIRATORS DURING THE CORONAVIRUS OUTBREAK

Under the Occupational Safety and Health Administration's (OSHA) respiratory protection standard, 1910.134(d)(1)(ii), all respirators that employers require workers to wear in the United States must be certified by the National Institute for Occupational Safety and Health (NIOSH).[1] NIOSH approves and certifies all respiratory protective devices, including filtering facepiece respirators, when manufacturers comply with the approval requirements under 42 CFR Part 84.[2] Manufacturers that successfully meet the requirements for approval and certification of any type of respirator are called "approval holders."

During the COVID-19 emergency, NIOSH-approved N95 respirators have been in short supply. To address these shortages, the Food and Drug Administration (FDA) and OSHA have relaxed requirements and permitted the use of certain imported non-NIOSH-approved N95 respirators during this time. But employers still are responsible for ensuring respirators provided comply with all relevant certifications and standards.

Below are government resources to help determine when imported respirators are protective and acceptable to use during the coronavirus outbreak. Workers or their representatives can use this fact sheet to doublecheck that employers are providing adequate respiratory protection.

Approved NIOSH Respirator Markings

NIOSH maintains a complete list of all approved filtering facepiece respirators, including N95s and surgical N95s (that also have been cleared by the FDA as a surgical mask). The alphabetical list includes the name of the manufacturer (approval holder), the model number, NIOSH approval number and the manufacturer's donning procedure instructions for respirator users.[3] Users should check this list to determine whether the N95 or other filtering facepiece respirator they have been provided is NIOSH approved.

Each individual filtering facepiece respirator approved by NIOSH is required to have specific information (markings) on the respirator.[4] Users should examine the respirator provided to be sure the following information is printed on the device:

- Name of approval holder/manufacturer business name, a registered trademark, or an easily understood abbreviation of the applicant/approval holder's business name as recognized by NIOSH. When applicable, the name of the entity to which the FFR has been private labeled by the approval holder may replace the approval holder business name, registered trademark or abbreviation of the approval holder business name as recognized by NIOSH.
- NIOSH in block letters or the NIOSH logo.
- NIOSH Testing and Certification approval number, e.g., TC-84A-XXXX.
- NIOSH filter series and filter efficiency level, e.g., N95, N99, N100, R95, P95, P99, P100.

- Model number or part number: The approval holder's respirator model number or part number, represented by a series of numbers or alphanumeric markings, e.g., 8577 or 8577A.

WARNING: Some manufacturers identify a NIOSH "TN" or Task Number on the packaging. This is a NIOSH registration number that tells a manufacturer that an application for approval has been submitted to NIOSH. The "TN" number cannot be used to verify any approval.

There is a problem with counterfeit filtering facepiece respirators reaching the market that falsely claim to be approved by NIOSH. Users can check the NIOSH counterfeit web page to help determine whether the respirator is NIOSH approved.[5,6] Signs that a respirator may be counterfeit include:

- No markings of any kind on the filtering facepiece respirator.
- No approval (TC) number on the filtering facepiece respirator or headband.
- No NIOSH markings.
- NIOSH spelled incorrectly.
- Presence of decorative fabric or other decorative add-ons (e.g., sequins).
- Claims of approval for children (NIOSH does not approve any type of respiratory protection for children).
- Filtering facepiece respirator has ear loops instead of headbands (devices with ear loops are difficult to fit).

N95 Shortage Responses by the FDA

NIOSH-approved N95 and surgical N95 filtering facepiece respirators have been in very short supply, especially for health care workers to use when providing care to patients suspected or known to be infected with COVID-19. In response to the shortage, and only for the duration of the coronavirus outbreak, the FDA has issued two Emergency Use Authorizations (EUAs) that permit the use of imported non-NIOSH-approved filtering facepiece respirators (FFRs) in health care settings that are manufactured to certain standards and classifications in foreign countries. FDA is involved with respiratory protection devices and other forms of personal protective equipment used in the health care industry if the devices are intended for medical purpose. FDA is not involved in such devices and equipment in industries outside of health care.

WARNING: Companies that have an application pending may have an FDA registration number. An FDA registration number is not an approval number. Use of this number on the packaging may be an indication that a product is not authentic.

FDA Emergency Use Authorizations for Imported Respirators from Countries Other Than China

The first EUA was issued on March 28, 2020.[7] It permits filtering facepiece respirators imported from the following countries (except the People's Republic of China) to be used in health care that are manufactured to the listed performance standards and product classifications contained in the table on the next page.

In addition, the FDA EUA permits disposable FFRs to be used in health care that have a marketing authorization from one of the following regulatory jurisdictions:

- European CE Mark
- Australian Register of Therapeutic Goods (ARTG) Certificate of Inclusion
- Health Canada Licence
- Japan Pharmaceuticals and Medical Device (PMDA)/ Ministry of Health Labour and Welfare (MHLW)

WARNING: The European CE Mark and the China Export Mark are very similar looking and can be easily confused. Review the marks closely to verify them.

Any respirator from any of the countries listed in the table below, except for those manufactured in the People's Republic of China, is authorized for use in health care settings as long as it is manufactured to the performance standard indicated and has the acceptable product classification. The Centers for Disease Control and Prevention (CDC) also has incorporated the table above as part of its crisis capacity strategies for the use of respirators from foreign countries in health care settings when there are shortages of NIOSH-approved N95s.[8] Under the March 28 EUA, additional foreign-manufactured respirators also can be authorized for use, and these respirators are posted periodically to Exhibit 1.[9] The list includes the manufacturer's name, respirator model(s) and country of manufacture. Users should check Exhibit 1 periodically to identify any additional FFRs that have been approved for use by the FDA under this EUA.

Respirators Approved Under Standards Used in Other Countries that are Similar to NIOSH-Approved N95 Filtering Facepiece Respirators

Country	Performance Standard	Acceptable Product Classification	May Be Used in Lieu of NIOSH-Certified Products Classified as
Australia	AS/NZS 1716:2012	P2	N95
		P3	N99 or lower
Brazil	ABNT/NBR 13698:2011	PFF2	N95
		PFF3	N99 or lower
People's Republic of China*	GB 2626-2006 GB 2626-2019 GB 19083-2010	KN/KP95	N95
		KN/KP100	N95
Europe	EN 149-2001	P2	N95
		P3	N99 or lower
Japan	JMHLW-2000	DS/DL2	N95
		DS/DL3	N99 or lower
Korea	KMOEL-2017-64	Special 1st	N95
Mexico	NOM-116-2009	N95	N95
		R95	R95 or lower
		P95	P95 or lower
		N99	N99 or lower
		R99	R99 or lower
		P99	P99 or lower
		N100	N100 or lower
		R100	R100 or lower
		P100	P100 or lower

*Covered by the FDA EUA issued on May 7, 2020.

Sources: www.fda.gov/media/136403/download; www.fda.gov/media/136664/download

FDA Emergency Use Authorizations for Imported Respirators from China

Out of concern that counterfeit respirators from the People's Republic of China may find their way into U.S. markets, the FDA issued a second EUA on May 7, 2020—a revision of the initial EUA issued on April 3, 2020.[10] Many of the respirators authorized under the April 3 EUA did not meet the minimum particulate filtration efficiency of 95%; they now have been removed from the list of authorized Chinese respirators found in Appendix A of the May 7 EUA. The EUA authorizes respirators from China that meet a certain performance standard and acceptable product classification (see the table above) to be used in health care settings during the COVID-19 emergency. These Chinese respirators must meet one of three separate criteria, including an additional criteria that requires the device has NIOSH testing results that indicate a minimum and maximum filtration efficiency greater than or equal to 95%.[11] The FDA has issued a "Letter to Health Care Providers" and a set of FAQs that help explain the May 7 EUA.[12,13]

The specific respirators from China authorized for use are listed in Appendix A of the EUA.[14] The list includes the manufacturer's name, respirator model(s) and country of manufacture. This list is updated as additional respirators from China are authorized for use by the FDA. Workers should check Appendix A frequently to identify *all* FFRs manufactured in China approved for use by the FDA. Users of FFRs manufactured in the People's Republic of China are

strongly advised to also check the NIOSH website on counterfeit respirators.[15]

If your employer is considering purchasing respirators from a foreign country, including respirators from China, the CDC has a website that provides the various factors to be considered when selecting foreign respirators, to ensure an authorized device is purchased.[16] Workers also should consult the CDC website, along with this fact sheet, whenever the purchase of foreign respirators is being considered.

NIOSH Filtration Efficiency Performance Assessments

NIOSH also is conducting filtration efficiency performance assessments on *some* of the international FFRs available in the United States that are not NIOSH approved, and posts the results on its website.[17] The postings include the name of the manufacturer, the model number, the international standard used to manufacture the respirator, the maximum and minimum filtration efficiency (%) results and a link to a copy of the complete test report. Some of the respirators in the listings have filtration efficiency results far below the 95% efficiency required for a NIOSH-approved N95 FFR; those respirators must not be used by workers.

Users should use this NIOSH website to see whether an imported FFR they may be assigned to wear has been tested by NIOSH, and whether it meets the 95% filtration efficiency criteria. If the device falls below 95% filtration efficiency, workers should *demand* the employer stop using the respirator and secure either a NIOSH-approved N95 or an imported FFR that has a filtration efficiency of 95% or greater. NIOSH has established a process for requesting an international respirator assessment to determine the filtration efficiency.[18] The agency also is aligning the international respirator assessments with the FDA EUAs, and only products listed on the EUAs will be considered. Requests from federal and state agencies, employers and health care systems will be accepted. Workers may want to ask their employer to request a NIOSH assessment if there are concerns about the filtration efficiency of any Chinese respirator that has not been assessed.

In addition, many of the tested respirators have ear loops instead of headbands—yet most devices with ear loops will not pass a fit test. Workers can look at the NIOSH test report and examine the picture(s) of the device to see whether the device is made with ear loops or headbands.

N95 Shortage Responses by OSHA

In response to the shortage of NIOSH-approved N95 FFRs, OSHA issued an interim enforcement guidance on April 3, 2020, that also permits the use of respirators certified under certain standards of other countries or jurisdictions identical to that of the FDA EUAs of March 28, 2020, and May 7, 2020, including those manufactured in the People's Republic of China.[19] This OSHA enforcement guidance applies *in all industries,* including workplaces in which:

- Health care personnel are exposed to patients with suspected or confirmed coronavirus disease 2019 (COVID-19) and other sources of SARS-CoV-2 (the virus that causes COVID-19).
- Protection of workers exposed to other respiratory hazards is impacted by the shortage resulting from the response to the COVID-19 pandemic. Such workplace respiratory hazards may be covered by one or more substance-specific health standards.

Employers in industries *outside of health care settings* should follow all of the recommended steps and checks of websites when purchasing a NIOSH-approved N95 FFR or importing a non-NIOSH-approved FFR. Users can utilize several resources, including the NIOSH listing of approved N95s[20] and NIOSH's counterfeit pages.[21,22] Likewise, when selecting an imported non-NIOSH-approved FFR, users should check NIOSH's counterfeit pages,[23,24] FDA Exhibit 1,[25] FDA Appendix A[26] and the NIOSH posting of filtration efficiency testing of international respirators.[27]

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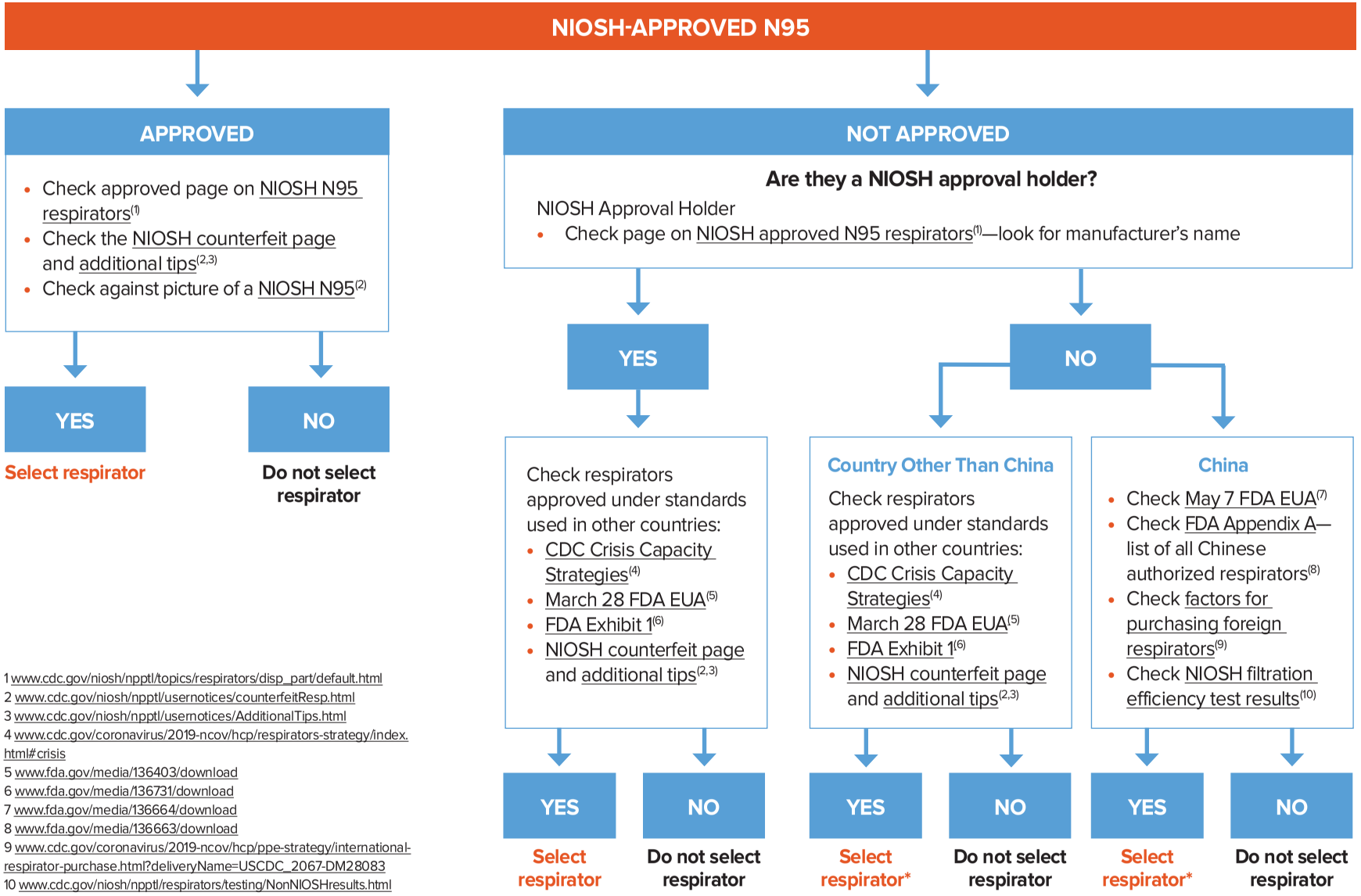
SELECTING A NIOSH-APPROVED OR FDA-AUTHORIZED N95 RESPIRATOR



1 www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html
2 www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html
3 www.cdc.gov/niosh/npptl/usernotices/AdditionalTips.html
4 www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html#crisis
5 www.fda.gov/media/136403/download
6 www.fda.gov/media/136731/download
7 www.fda.gov/media/136664/download
8 www.fda.gov/media/136663/download
9 www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/international-respirator-purchase.html?deliveryName=USCDC_2067-DM28083
10 www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html

*Non-NIOSH-approved products developed by manufacturers who are not NIOSH approval holders, including only products approved by and received from China, should not be used during aerosol-generating procedures.

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Endnotes

1 OSHA respiratory protection standard, 1910.134(d)(1)(ii), *available at* www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134.
2 NIOSH respirator approval and certification requirements, 42 CFR Part 84, *available at* www.cdc.gov/niosh/npptl/RespApprovalInfo.html.
3 NIOSH-Approved Particulate Filtering Facepiece Respirators, *available at* www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html.
4 Ibid.
5 NIOSH Counterfeit Respirators/Misrepresentation of NIOSH Approval, *available at* www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html.
6 Additional Tips for Spotting Counterfeit Respirators, *available at* www.cdc.gov/niosh/npptl/usernotices/AdditionalTips.html.
7 March 28, 2020, FDA EUA Imported Non-NIOSH Approved FFRs, *available at* www.fda.gov/media/136403/download.
8 CDC Crisis Capacity Strategies, When N95 Supplies Are Running Low, *available at* www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html#crisis.
9 Exhibit 1, *available at* www.fda.gov/media/136731/download.
10 May 7, 2020, FDA EUA Imported FFRs Manufactured in China, *available at* www.fda.gov/media/136664/download.
11 A disposable non-NIOSH-approved respirator manufactured in China that meets one of the following criteria is eligible for authorization under this EUA:

1. It is manufactured by an entity that holds one or more NIOSH approvals for other models of FFRs produced in accordance with the applicable standards of authorization in other countries that can be verified by FDA.
2. It has a regulatory authorization under a jurisdiction, including the Chinese National Medical Products Administration (NMPA) registration certification by an appropriate provincial or municipal regulatory authority, that can be authenticated and verified by the FDA.
3. It was previously listed in Appendix A under the April 3, 2020, letter of authorization as an authorized respirator because it demonstrated acceptable performance to applicable standards as documented by test reports, has had particulate filtration efficiency assessed by NIOSH using a modified version of NIOSH's Standard Test Procedure (STP) TEBAPR-STP-0059 within 45 calendar days of the date of issuance of this EUA, and has results of NIOSH testing that indicate a minimum and maximum filtration efficiency greater than or equal to 95%.

12 Letter to Health Care Providers, *available at* www.fda.gov/medical-devices/letters-health-care-providers/certain-filtering-facepiece-respirators-china-may-not-provide-adequate-respiratory-protection-letter.
13 FAQs on EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic, *available at* www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic.
14 Appendix A, *available at* www.fda.gov/media/136663/download.
15 NIOSH Counterfeit Respirators/Misrepresentation of NIOSH Approval, *available at* www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html.
16 Factors to Consider When Planning to Purchase Respirators From Another Country, Including KN95 Respirators From China, *available at* www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/international-respirator-purchase.html?deliveryName=USCDC_2067-DM28083.
17 International Assessment Results—Not NIOSH-approved, *available at* www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html.
18 International Respirator Assessment Request, *available at* www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSH.html.
19 OSHA April 3, 2020, Enforcement Guidance for Use of Respiratory Protection Equipment Certified Under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic, *available at* www.osha.gov/memos/2020-04-03/enforcement-guidance-use-respiratory-protection-equipment-certified-under#_ftnref6.
20 NIOSH-approved particulate filtering facepiece respirators, available at www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html.
21 NIOSH Counterfeit Respirators/Misrepresentation of NIOSH Approval, available at www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html.
22 Additional Tips for Spotting Counterfeit Respirators, available at www.cdc.gov/niosh/npptl/usernotices/AdditionalTips.html.
23 NIOSH Counterfeit Respirators/Misrepresentation of NIOSH Approval, available at www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html.
24 Additional Tips for Spotting Counterfeit Respirators, available at www.cdc.gov/niosh/npptl/usernotices/AdditionalTips.html.
25 Exhibit 1, available at www.fda.gov/media/136731/download.
26 Appendix A, available at www.fda.gov/media/136663/download.
27 International Assessment Results—Not NIOSH-approved, available at www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html.