



Respiratory protection: A closer look at FEMA- imported respirators from Asia

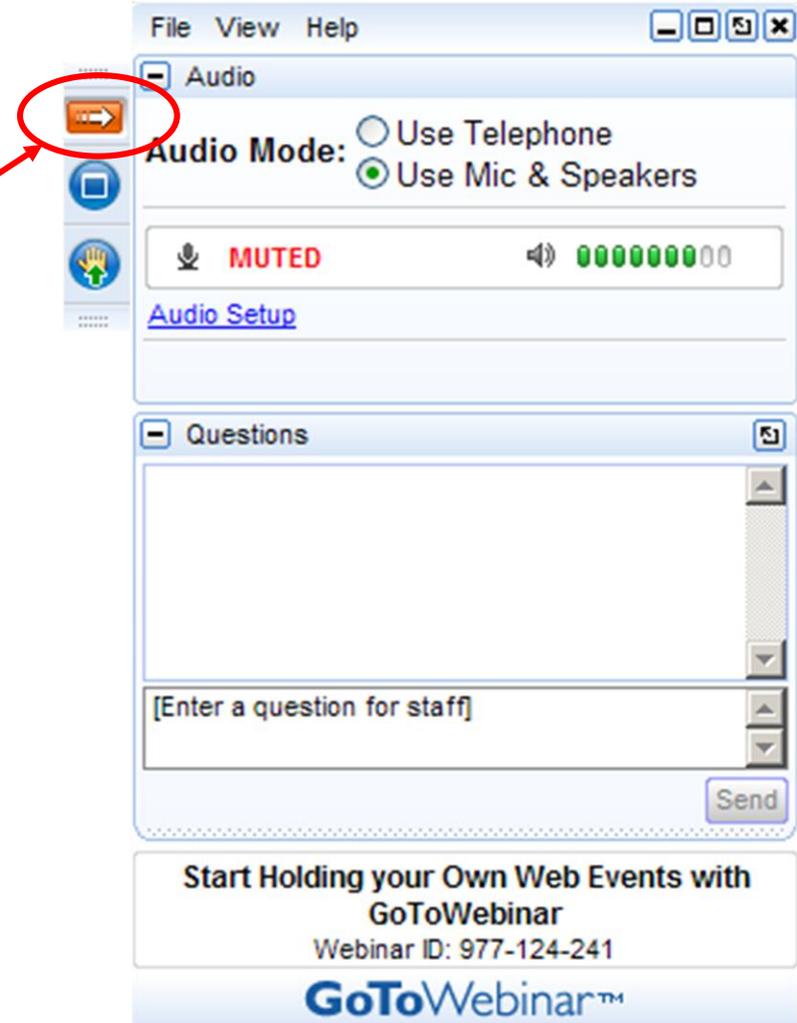


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Housekeeping.

Asking a question from the GoToWebinar page:

- Click on the orange box with a white arrow to expand your control panel (upper right-hand corner of your screen)
- Type a question in the question box and click send



Disclosure.

Jessica works as an Application Engineer in 3M's Personal Safety Division

Agenda.

- 1. Review of webinars 1 and 2 in series**
- 2. How FEMA will distribute**
- 3. Resources to help you prepare for FEMA imports**
- 4. Overview of FEMA-imported filtering facepiece models**
- 5. Where to find employee training materials**
- 6. Q & A**

Respiratory Protection.

This presentation is based on current United States federal requirements and recommendations as of May 2020. State, local or other country requirements may be different.

Always consult *User Instructions* and follow local laws and regulations.

Review: Part 1 and 2 of Series

Respiratory Protection. Types



Procedure Mask

Loose



Surgical Mask

Loose



Filtering Facepiece Respirators (FFRs), such as N95

Snug



Elastomeric Respirator

Snug



Powered Air Purifying Respirator (PAPR)

Loose

Helps reduce wearer's exposure to airborne particles

Components can be disinfected & reused



- The Occupational Safety and Health Administration (OSHA) has a respiratory protection standard (29 CFR 1910.134) that specifies the requirements for employers assigning respiratory protection to workers.
- Requirements include: medical evaluations & fit testing



- The National Institute of Occupational Safety and Health (NIOSH) tests and approves respirators in the US
- Testing/certification is based on the respirators' physical and performance characteristics



- Surgical masks and surgical respirators are cleared for use as medical devices by the U.S. Food and Drug Administration (FDA)

CDC Recommendations. N95 respirator use

Conventional capacity strategies

- Decrease exposure through barriers, distancing, telemedicine.
- Utilization of alternative respirators: PAPR, elastomeric, etc.

Contingency capacity strategies

- Already implemented conventional capacity strategies.
- Could include: Suspending annual fit testing, extended use of N95s.

Crisis capacity strategies

- Already implemented conventional and contingency capacity strategies.
- Use of N95s past their shelf life, Use of respirators from other countries (non-NIOSH approved), limited reuse
- Decontamination and subsequent reuse of FFRs should only be practiced as a crisis capacity strategy.

CDC Recommendations. Crisis capacity strategy

Decontamination and reuse of filtering facepiece respirators:

- Only employed as a crisis capacity strategy
- CDC and NIOSH do not recommend decontamination and reuse of FFRs in Standard care.

Virus survives up to

72

hours on a variety
of surfaces

One mitigation strategy:



1



2



3



4



5

3M has Completed Testing Regarding the Following Methods*:

Decontamination Method	3M N95 Model Evaluated	Cycles Tested	Filtration Efficiency & Fit Related Evaluation	US FDA EUA Issued
Vaporized hydrogen Peroxide: Steris V-PRO	1860, 8210, 1870+	10	Pass	
Vaporized hydrogen Peroxide: ASP, STERRAD®	1860, 8210,	2	Pass	
Vaporized hydrogen Peroxide: Steriluent	1860, 8210, 1804	10	Pass	
Vaporized hydrogen Peroxide: Battelle	1860, 8210, 1804	3	Pass	

Other decontamination methods have passed 3M's testing for filtration efficiency and fit, for certain models of 3M FFRs, but do not have an FDA Emergency Use Authorization (EUA), at this time. For more information, see 3M technical bulletin linked below.

* For more information regarding decontamination methods, cycles, and FFRs tested, please see [3M Technical Bulletin](#) which is updated as new information is received. 3M does not test for decontamination efficacy.

General infection prevention

- Stay home if sick
- Practice good hand hygiene

Fit test setup

- Subjects should stand 6 feet apart
- Fit tester should wear respirator since close proximity required

Disinfection Considerations

- Use same hood for each subject's sensitivity and fit tests
- Use one set of nebulizers for each person being fit tested
- Disinfect outside of nebulizer nozzle and inside of hood between each fit test

Quantitative fit testing with 601 Adapter

- Disinfect narrow tube that gets inserted into respirator



General strategies

for skin damage prevention

Choose FFR that fits comfortably

Do not over-tighten FFR

Place FFR headbands correctly

Don't ignore pain

Remove tight-fitting facial PPE every 2 hours* if possible

Protect skin from moisture and friction

Prevention | 3M^(TM) Cavityon^(TM) No Sting Barrier Film

Management | 3M^(TM) Cavityon^(TM) Advanced Skin Protectant

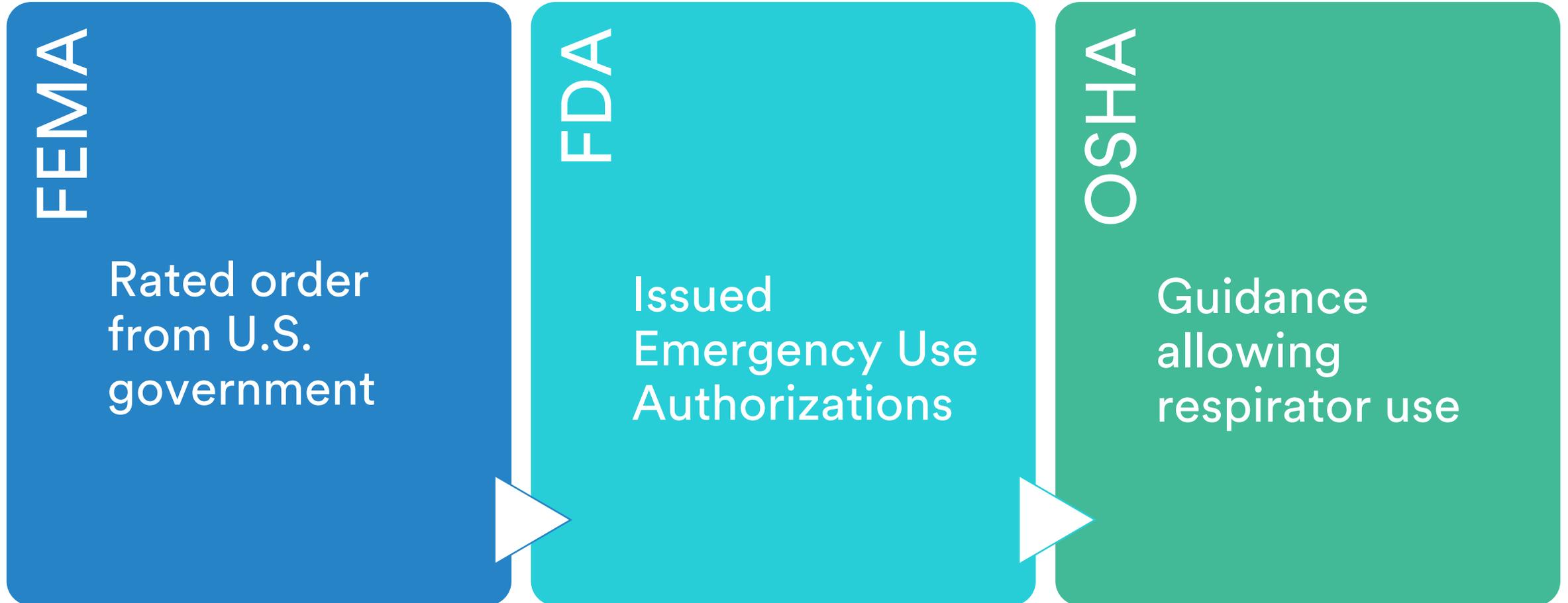


*NPIAP. NPIAP Position Statement on Preventing Injury with N95 Masks. 2020.

How FEMA will distribute

Regulatory Framework.

For FEMA to import PPE from Asia



Resources:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>

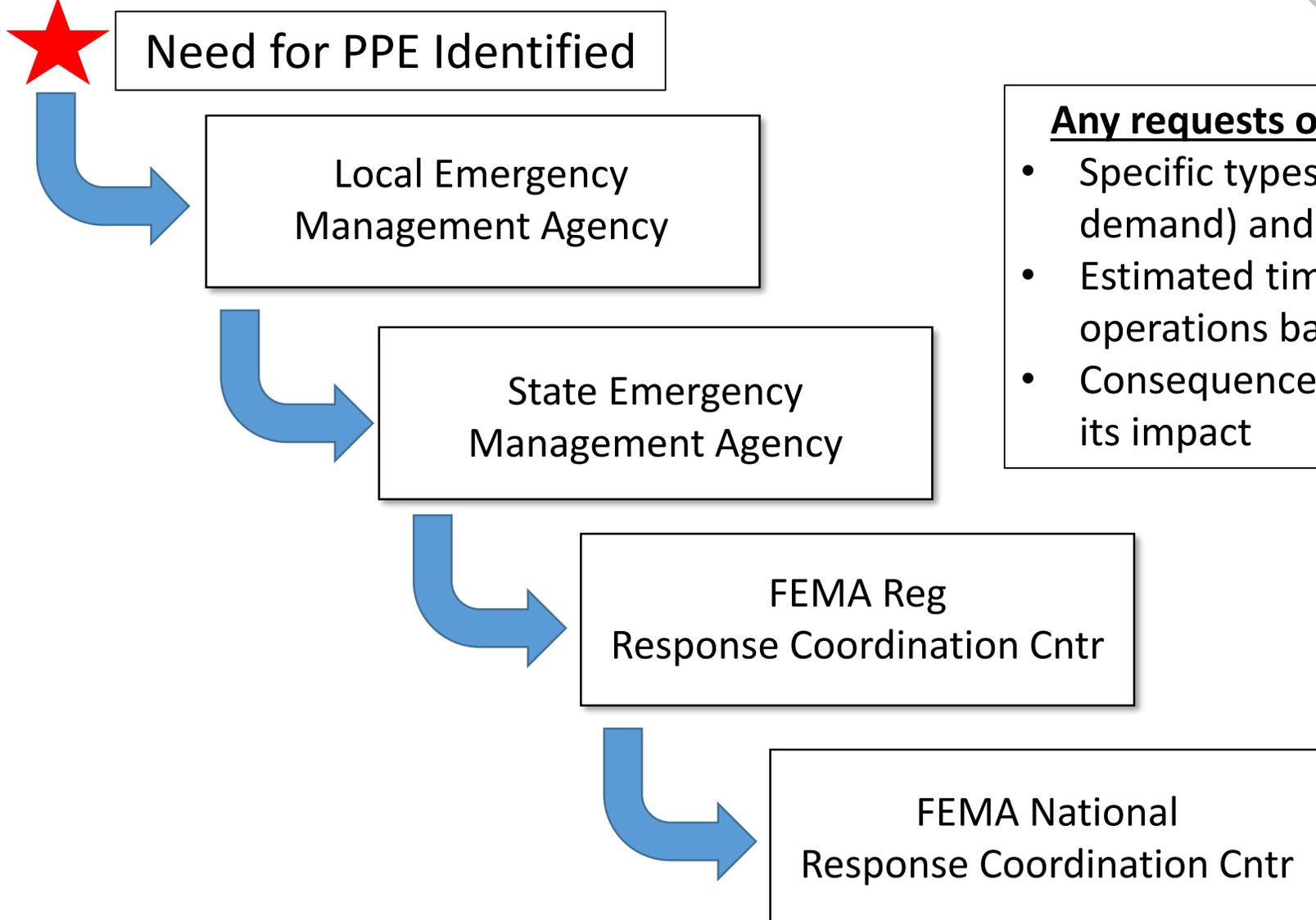
<https://www.osha.gov/memos/2020-04-03/enforcement-guidance-use-respiratory-protection-equipment-certified-under>

How to Acquire.

FEMA to distribute



FEMA



- Any requests of urgent resupply should include:**
- Specific types, quantities (30, 60, and 90-day demand) and locations where PPE is needed
 - Estimated time until shortage impacts operations based on PPE usage rate
 - Consequences of the shortage and duration of its impact





Reference

April, 2020

3M Respirators in International Packaging Made Available in US during COVID-19

Non-NIOSH Approved Respirators Emergency User Authorization (EUA) End User Information

The following 3M respirators are listed in Appendix A of the April 3rd, 2020 EUA title imported, "Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China". **Users should read the information below for their model before use. Please note these are also listed at [3M.com/coronavirus](https://www.3m.com/coronavirus).**

- [9552/9552V, 9502, 9542, 9542V](#)
- [9501, 9501+/9501V+, 9505+, 9541, 9541V](#)
- [9001/9002](#)
- [9502+/9502V+](#)
- [8822 \(AU\), 8822 \(K\) and 8205J](#)
- [9320+ and 9322+](#)

<https://multimedia.3m.com/mws/media/18293400/3m-respirators-in-international-packaging-made-available-in-us-during-covid-19.pdf>

China - KN95

User Instructions

- [3M™ Particulate Respirator 9541](#)
- [3M™ Particulate Respirator 9541V](#)
- [3M™ Particulate Respirator 9542](#)
- [3M™ Particulate Respirator 9542V](#)
- [3M™ Particulate Respirator 9505+](#)
- [3M™ Particulate Respirator 9552](#)
- [3M™ Particulate Respirator 9552V](#)
- [3M™ Particulate Respirator 9501](#)
- [3M™ Particulate Respirator 9501+](#)
- [3M™ Particulate Respirator 9501V+](#)
- [3M™ Particulate Respirator 9502](#)
- [3M™ Particulate Respirator 9502+](#)
- [3M™ Particulate Respirator 9502V+](#)

Authenticity.

Are FFRs from Asia authentic?



FEMA-acquired 3M respirators from Asia are distributed by FEMA.

If the respirator is one of the model numbers identified on the 3M website and was distributed for free and can be traced to a FEMA source of supply, it is more likely to be an authentic 3M product.

FEMA is the only entity that is acquiring significant quantities of 3M respirators directly from 3M in Asia and then importing and distributing those models of respirators in the United States.

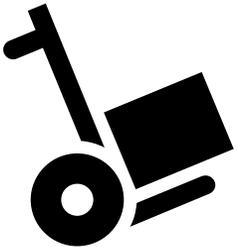
If still unsure, contact the 3M fraud hotline at 1 (800) 426-8688 or visit the 3M fraud website at www.Go.3M.com/covidfraud.

Resources:

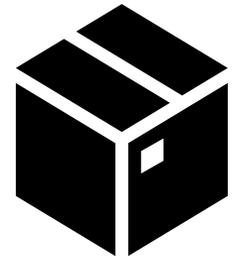
<https://multimedia.3m.com/mws/media/18036700/fraudulent-activity-price-gouging-and-counterfeit-products.pdf>

3M Respirators

- Should be sold only in 3M packaging, with model-specific user instructions accompanying the product.
- Should not be sold individually or without packaging (including User Instructions).
- Have strict quality standards, and therefore products that have missing straps, strange odors, blocked valves, misspelled words, etc. are likely not authentic 3M respirators.
- Are intended, labeled, packaged, and certified to meet the requirements of the countries in which 3M sells it (requirements differ around the world)



3M recommends purchasing our products only from a 3M authorized distributor or dealer, as that increases the likelihood that you will receive authentic 3M products.



Additional 3M Fraud Resources:

- 3M COVID-19 Fraud hotline: 1 (800) 426-8688
- Webpage: www.go.3m.com/covidfraud (also have webpages for Canada)

Resources on FEMA imports



Go to bCom Log in | Help

3M.com/airlift

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United States > 3M Safety > Worker Health & Safety > Covid19 > China KN95 Respirators Imported and Distributed by FEMA

Worker Health & Safety

OVERVIEW | PRODUCTS | SOLUTIONS | TRAINING | RESOURCES | SUPPORT

Alert: 3M is committed to the fight against COVID-19. [Learn about the actions we are taking here.](#)



3M Respirators in International Packaging Made Available in US during COVID-19

3M is continuing to address the COVID-19 pandemic with many tactics to help protect those responding to the outbreak, including... April, 3M reached agreement with the U.S. government on a plan that, with the Trump Administration's assistance, will enable... States over a 3-month period starting in April, from our plants in Asia.

Read this if you have received 3M respirators in international packaging

The Food and Drug Administration requires this information be made available to everyone who has received these respirators.

[Key Reference Information](#)



Technical Bulletin

April, 2020

Respirators from Asia Imported and Distributed by FEMA

Description

3M, in response to a rated order from the U.S. Federal Emergency Management Agency (FEMA) under the U.S. Defense Production Act, is supplying 3M respirators manufactured in Asia to FEMA, which is distributing them to help bolster the supply of filtering facepiece respirators (FFR) in the U.S. The U.S. Food and Drug Administration (FDA) has issued two Emergency Use Authorizations (EUAs) authorizing the use of respirators approved to other countries' standards in U.S. healthcare workplaces, per guidance from the U.S. Centers for Disease Control and Prevention (CDC) in their [Strategies for Optimizing the Supply of N95 Respirators](#). Additionally, the U.S. Occupational Safety and Health Administration (OSHA) has issued enforcement guidance allowing the [use of respirators approved to certain standards in other countries](#).



FEMA-imported respirator models

Respirator Models.

Types being imported



Unvalved KN95



Valved KN95



Cup Shaped



Flat fold with Headbands



Unvalved KN90

Important Notes:

- Some models are the same as U.S. models
- FEMA is importing respirators from other manufacturers also

Resource: 3M's [FEMA-Imported Respirator Table](#)

FEMA-Imported FFRs.

Approvals information

3M.com/airlift

[DOWNLOAD TECHNICAL BULLETIN \(PDF, 1.6 MB\)](#)

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Technical Bulletin

January, 2020
Revision 2

Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes

Description

Filtering facepiece respirators (FFR), which are sometimes called disposable respirators, are subject to various regulatory standards around the world. These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular standard. During pandemic or emergency situations, health authorities often reference these standards when making respirator recommendations, stating, for example, that certain populations should use an “N95, FFP2, or equivalent” respirator.

This document is only intended to help clarify some key similarities between such references, specifically to the following FFR performance standards:

- N95 (United States NIOSH-42CFR84)
- FFP2 (Europe EN 149-2001)
- KN95 (China GB2626-2006)
- P2 (Australia/New Zealand AS/NZA 1716:2012)
- Korea 1st class (Korea KMOEL - 2017-64)
- DS (Japan JMHLW-Notification 214, 2018)

As shown in the following summary table, respirators certified as meeting these standards can be expected to function very similarly to one another, based on the performance requirements stated in the standards and confirmed during conformity testing.



Unvalved KN95

[VIEW UNVALVED KN95 PRODUCT INFORMATION](#)



Valved KN95

[VIEW VALVED KN95 PRODUCT INFORMATION](#)



Cup Shaped

[VIEW CUP SHAPED PRODUCT INFORMATION](#)

[3M.com/airlift](https://www.3m.com/airlift)

Unvalved KN95 [View full comparison chart >](#)

Model Number	Certification(s)	Color	Band Style	NIOSH Approval / EUA	Instructional Video	User Instructions
9010	NIOSH N95	White	Headbands	TC-84-4243	Vertical Flatfold Video	9010 UI
9552	KN95 (China)	White	Headband	April 3rd FDA EUA Appendix A	Vertical Flatfold Video	9552 UI
9132	NIOSH N95 KN95 (China)	Blue	Headband	TC-84-4243	Vertical Flatfold Video	Pending

Valved KN95 – Imported from China

Example Image*				
Model Number	9501V+	9541V	9542V	9552V
N95 Comparable	x	x	x	x
Certification(s)	KN95 (China)	KN95 (China)	KN95 (China)	KN95 (China)
Color	White	Gray	Gray	White
Band Style	Earloop	Earloop	Headband	Headband
NIOSH Approval/ EUA	April 3rd FDA EUA Appendix A			
Instructional Video	Pending	Pending	Vertical Flatfold	Vertical Flatfold
User Instructions	9501V+ UI	9541V UI	9542V UI	9552V UI



FEMA-Imported FFRs.

Understanding KN95 and KN90



N95

U.S. approval

APF 10

≥ 95% filtration efficiency

Govt. Recommended respirator for COVID-19 response



KN95

China approval

APF 10

≥ 95% filtration efficiency

Govt. Recommended respirator for COVID-19 response



KN90

China approval

APF 10

> **90%** filtration efficiency

NOT Govt. Recommended respirator for COVID-19 response

Similarities

- 2 bands and a nose clip
- Some are same as common U.S. models
 - Note - packaging will be in Asian languages
- Fit testing should be conducted

Differences

- Vertical Flatfold design uncommon in U.S.
- Earloops not featured on U.S. respirators
- Designed for facial features common in Asia
- May not fit as well as respirators designed for US

FEMA-Imported FFRs.



Earloops

In the US earloops are not on NIOSH-approved respirators (headbands)

Outside the US 3M does manufacture some certified respirators with earloops

Respirators with earloops are designed for facial features common in Asia

NIOSH states users must ensure a proper fit is achieved

Resources:

<https://multimedia.3m.com/mws/media/18321500/3m-filtering-facepiece-respirators-imported-to-u-s-from-asia-by-fema.pdf>

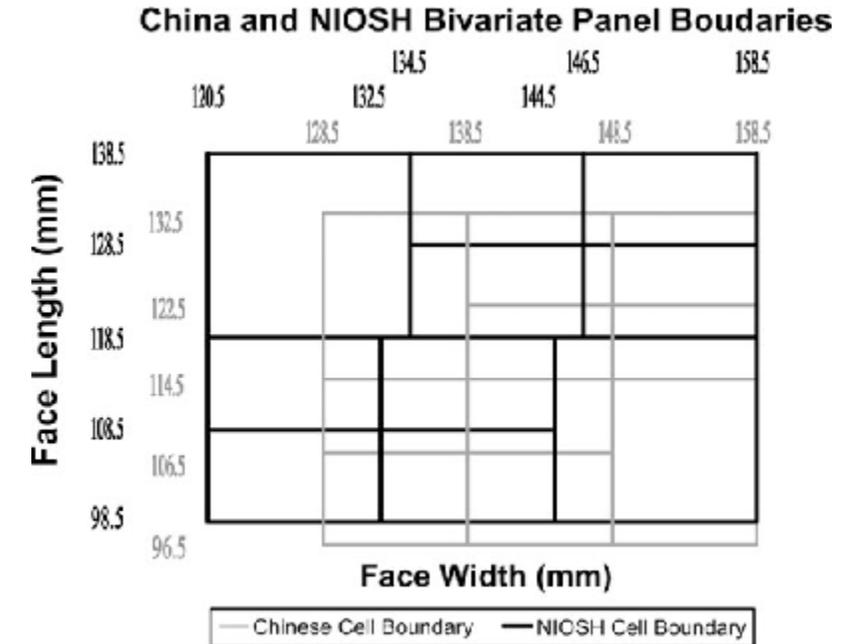
FEMA-Imported FFRs.

Will they fit my workforce?

It depends

- Some imported models have different design than U.S. respirators
- Those with different facial features may not be able to achieve a satisfactory fit
- U.S. customers may experience lower fit test pass rates

If a fit test cannot be conducted, or the wearer cannot pass a fit test, then these products should be used as a facemask, not a respirator.



Chen, Weihong & Zhuang, Ziqing & Benson, Stacey & Du, Lili & Yu, Dan & Landsittel, Douglas & Wang, Limin & Viscusi, Dennis & Shaffer, Ronald. (2009). New Respirator Fit Test Panels Representing the Current Chinese Civilian Workers. The Annals of occupational hygiene. 53. 297-305. 10.1093/annhyg/men089.

Employee training materials

U.S. OSHA respirator standard mandates training and a fit test prior to the first time using a new respirator model.

Always read and follow all user instructions and conduct a user seal check.

Conduct fit testing the same way as N95 respirators typically sold and used in the U.S.

*qualitative fit testing using Bitrex™ or saccharin

*quantitative fit testing using a TSI PortaCount®

Respirator fit testing resources can be found on https://www.3m.com/3M/en_US/worker-health-safety-us/covid19/#fit-test-resources.

3M.com/airlift

Unvalved KN95 [View full comparison chart](#) ▶

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Certification(s)	KN95 (China)	KN95 (China)	KN95 (China)	KN95 (China)
Color	White	Gray	Gray	White
Band Style	Earloop	Earloop	Headband	Headband
NIOSH Approval/ EUA	April 3rd FDA EUA Appendix A	April 3rd FDA EUA Appendix A	April 3rd FDA EUA Appendix A	April 3rd FDA EUA Appendix A
Instructional Video	Vertical Flatfold Earloop	Vertical Flatfold Earloop	Vertical Flatfold	Vertical Flatfold
Poster	Vertical Flatfold EL	Vertical Flatfold EL	Vertical Flatfold HB	Vertical Flatfold HB
User Instructions	9501V+ UI	9541V UI	9542V UI	9552V UI

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Vertical Flat-fold with Earloop
Wear it Right
April 2020

Prepare to Use Respirator

1. With nosepiece facing away from you, hold the earloop strap in each hand with the nosepiece up.

Place Respirator on Face

2. Position the respirator under the chin.

Adjust the Metal Nose Strip

4. Place the fingertips of both hands at the top of the metal nosepiece. Mold the nosepiece to the shape of the nose bridge by pushing inward while moving your fingertips down both sides of the nosepiece. Pinching the respirator nosepiece using one hand may result in improper fit and less effective respirator performance. Use two hands.

Check the Respirator-to-Face Seal

5. The seal of the respirator on the face should be checked by the wearer prior to entering the work area.
 - a. Cover the front of the respirator with both hands, being careful not to disturb the position of the respirator.
 - b. Exhale sharply. If air leaks around the nose bridge, readjust the nosepiece as described in Step 4. If air leaks at the respirator edges, work the straps back along the side of your head. If you CANNOT achieve a proper seal, DO NOT enter the contaminated area. See your supervisor.
 - c. If no leakage is detected, then work may proceed.

Position the respirator under the chin



Thank you.
Questions?