Technical Guidance: **N95 Respirator**

Updated June 2, 2020

U.S. FDA reference info:
Classification: Class II
Product codes:

- MSH (respirator, surgical)
- ONT (N95 respirator with antimicrobial/antiviral agent)
- ORW (N95 respirator with antimicrobial/antiviral agent for use by the general public in public health medical emergencies)
- NZJ (respirator, N95, for use by the general public in public health medical emergencies)

Overview

The purpose of this technical guidance document is to provide the following information:

- Section 1: A concise introduction to the key design features of an N95 respirators, including a brief explanation of why each feature is important and how it is tested
- Section 2: Procurement guidance that may aid in the selection of N95 suppliers, as well as visual inspection and sample testing guidance to guard against the inadvertent use of counterfeit (mislabeled) product
- Section 3: Recommendations for preserving N95 respirator supplies by implementing extended use and/or reuse

Contents

1) Overview of Technical Features and Use Criteria

This section provides a concise introduction to the key design features of and use criteria for N95 respirators, including a brief explanation of why each feature is important and how it is tested (as applicable). Collectively, this set of technical features and use criteria are what ensure the safety and effectiveness of the respirator.

The three most important criteria that are required for a respirator to be effective are [1]:

1. Proper use: the respirator must be donned and doffed properly, and worn throughout exposure
2. Fit: the respirator must fit snugly to create a proper seal around the edges of the respirator
3. Filtration: the ability of the respirator to capture particles as they pass through the respirator

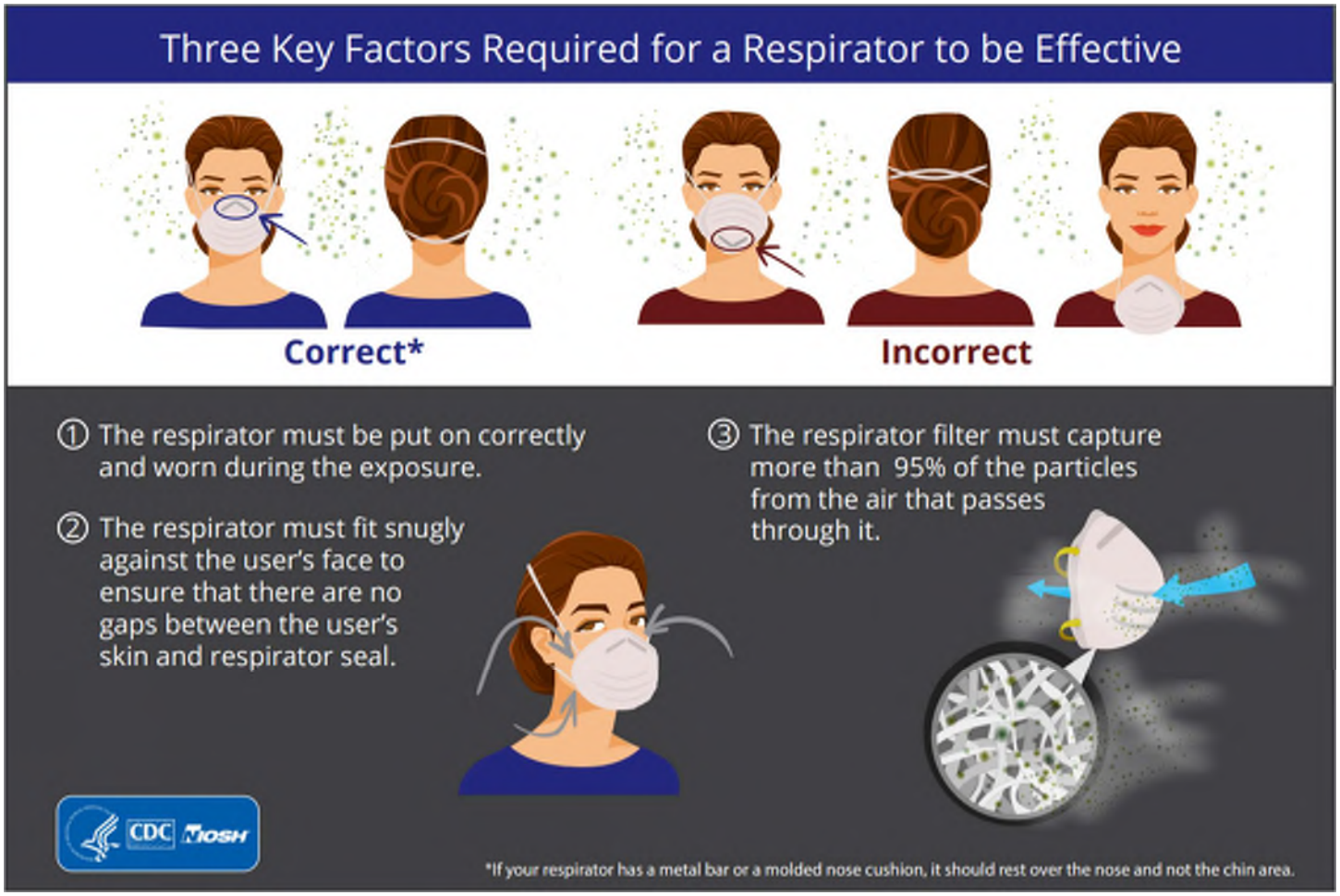


Figure 1 - https://www.cdc.gov/niosh/npptl/pdfs/KeyFactorsRequiedResp01042018-508.pdf

Proper Use

It is important for users to remember to wash their hands before donning or doffing the respirator. Follow the specific instructions provided with the respirator.

Donning

Properly donning the respirator is the first step toward achieving the proper fit. Here is some basic guidance to follow:

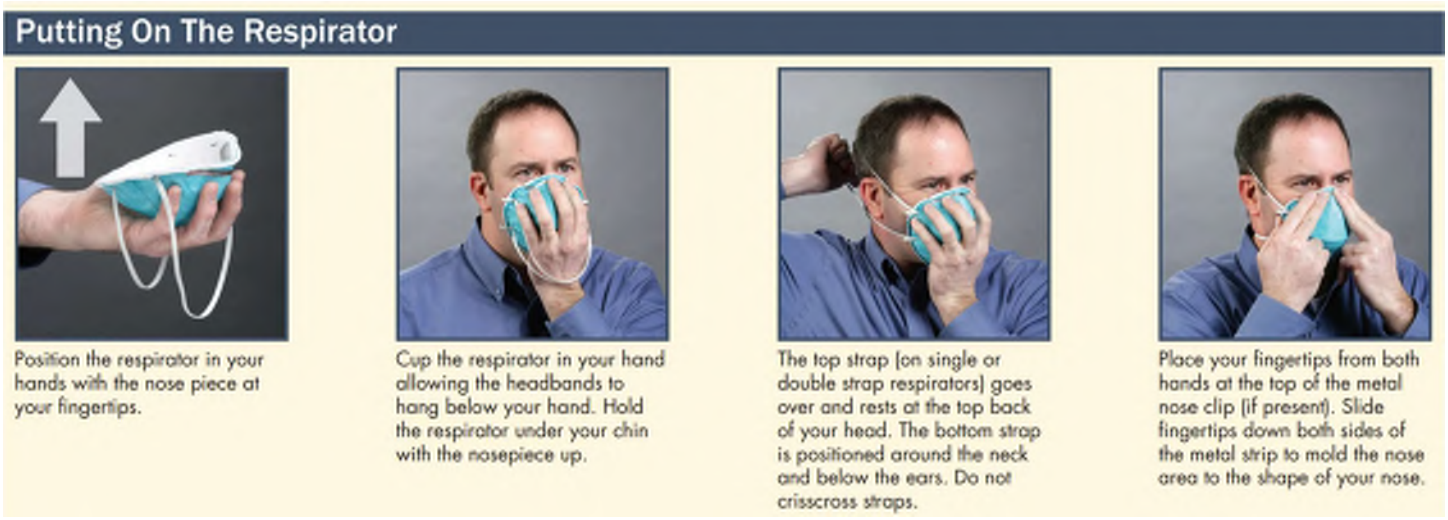


Figure 2 - Putting on the Respirator: https://www.cdc.gov/niosh/docs/2010-133/pdfs/2010-133.pdf

Doffing

Doffing the respirator is not an insignificant aspect to overlook. As the front of the respirator may be contaminated, it is important to remove it by only manipulating the straps.

Figure 3 - Removing Your Respirator: https://www.cdc.gov/niosh/docs/2010-133/pdfs/2010-133.pdf

Fit

Achieving a proper fit is important to ensure that minimal leakage occurs around the edges of the respirator when the user inhales; the intent is for the inhaled air to be directed through the respirator filter.

Securing Mechanism

NIOSH-approved N95 respirators typically have head bands. Respirators with an ear loop designs are inherently difficult to achieve a proper fit. There are currently no NIOSH-approved products with ear loops [2]. A fit test should be performed to help ensure that air does not leak around the mask edges; if it does, the straps should be adjusted.

Adjustable Nose Piece

If the respirator has an adjustable nose piece, adjust it to properly follow the contours of the nose and surrounding area. A fit test should be performed to help ensure that air does not leak around the nose.

Facial Hair

Respirators that rely on a tight seal around the facepiece should not be worn by those who have facial hair that interferes with the sealing surface. Facial hair that lies along the sealing area of a respirator (such as beards, sideburns, or some mustaches) will impair the integrity of the seal by creating a bypass through the facial hair. The facial hair itself

is not a sufficient air filter; the facial hair is not dense enough and the individual hairs are too large to capture particles like an air filter does [3].

Fit test method: Refer to Appendix D for a qualitative fit test procedure recommended by 3M.

Seal check (refer to the manufacturer's recommendations):

Figure 4 – Checking your Seal: https://www.cdc.gov/niosh/docs/2010-133/pdfs/2010-133.pdf

More detailed guidance for a seal check may be found here: https://www.cdc.gov/niosh/docs/2018-130/pdfs/2018-130.pdf?id=10.26616/NIOSHPUB2018130

Filtration

The "95" designation of the N95 respirator indicates that they are intended to filtrate at least 95% of airborne particles that are greater than 0.3 μm in size.

Test method: NIOSH procedure number TEB-APR-STP-0059, Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air-Purifying Respirators Standard Testing Procedure (STP).

Video of test overview: https://commons.wikimedia.org/w/index.php?title=File%3AWhat_it_Means_to_be_NIOSH-Approved_-_A_look_into_N95_Certification_Testing.webm

Respirator Series Classification (N, R, or P)

The "N" designation of the N95 respirator indicates that the respirator is not resistant to oil. An alternative "R" designation (e.g. R95) indicates that the respirator is resistant to oil. A "P" designation indicates that the respirator is oil-proof.

Inhalation and Exhalation Resistance

The inhalation and exhalation resistance is assessed to ensure the breathability of the respirator. To pass:

- The resistance upon initial inhalation shall not exceed 35 mm water-column height pressure when tested at a flow rate of 85 liters per minute
- The resistance upon initial exhalation shall not exceed 25 mm water-column height pressure when tested at a flow rate of 85 liters per minute

Test methods: NIOSH procedure numbers
TEB-APR-STP-0007, Determination of Inhalation Resistance Test, Air-Purifying Respirators Standard Testing Procedure
and
TEB-APR-STP-0003, Determination of Exhalation Resistance Test, Air-Purifying Respirators Standard Testing Procedure

Exhalation Valve

An exhalation valve will make it more comfortable for the wearer to exhale, but it is important to recognize that this exhaled breath is unfiltered. The CDC advises that, "respirators with exhalation valves should not be used in situations where a sterile field must be maintained (e.g., during an invasive procedure in an operating or procedure room) because the exhalation valve allows unfiltered exhaled air to escape into the sterile field [4]."

If an exhalation valve is provided, the following test procedure is applicable.
Test method: NIOSH procedure number TEB-APR-STP-0004, Determination of Exhalation Valve Leakage Test, Air-Purifying Respirators Standard Testing Procedure.

Natural Rubber Latex

Due to reports of allergic reactions, some medical device manufacturers started labeling products as "latex-free," "does not contain natural rubber latex," or "does not contain latex." However, it is not possible to reliably assure the complete absence of the allergens associated with the reactions to natural rubber latex. Therefore, the U.S. FDA advises manufacturers who want to indicate that natural rubber latex was not used in the manufacturing of their product to "inform users that a product, product container, or product packaging was not made with natural rubber latex [5]."

Flame-Resistance

If the respirator is to be used in an environment where fire is foreseeable hazard (e.g. during surgery), then it is recommended that the respirator can pass a flammability test [6].

Test method: Test the flammability per an industry standard such as 16 CFR 1610, Standard for the Flammability of Clothing Textiles

2) Procurement Guidance

This section is intended to provide guidance for procuring N95 respirators from unfamiliar suppliers. Unfortunately, it is important to be aware of the possibility that counterfeit or misrepresented (mislabeled) N95 respirators may be found on the market; such falsely marketed or counterfeit respirators may not be capable of providing appropriate respiratory protection.

Counterfeit Respirators / Misrepresentation of NIOSH-Approval

The CDC has compiled a set of guidance for detecting counterfeit or misrepresented NIOSH respirators. As a first line of defense, refer to the guidance provided to help spot counterfeit respirators before purchase: https://www.cdc.gov/niosh/npptl/usernotices/AdditionalTips.html (refer to Appendix A for translation)

All NIOSH-approved respirators are required to have an approval label on the respirator itself or within its packaging. Through visual inspection, it may be possible to identify signs that the respirator may be counterfeit. Please refer to the latest CDC guidance provided here: https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html (refer to Appendix B for translation)

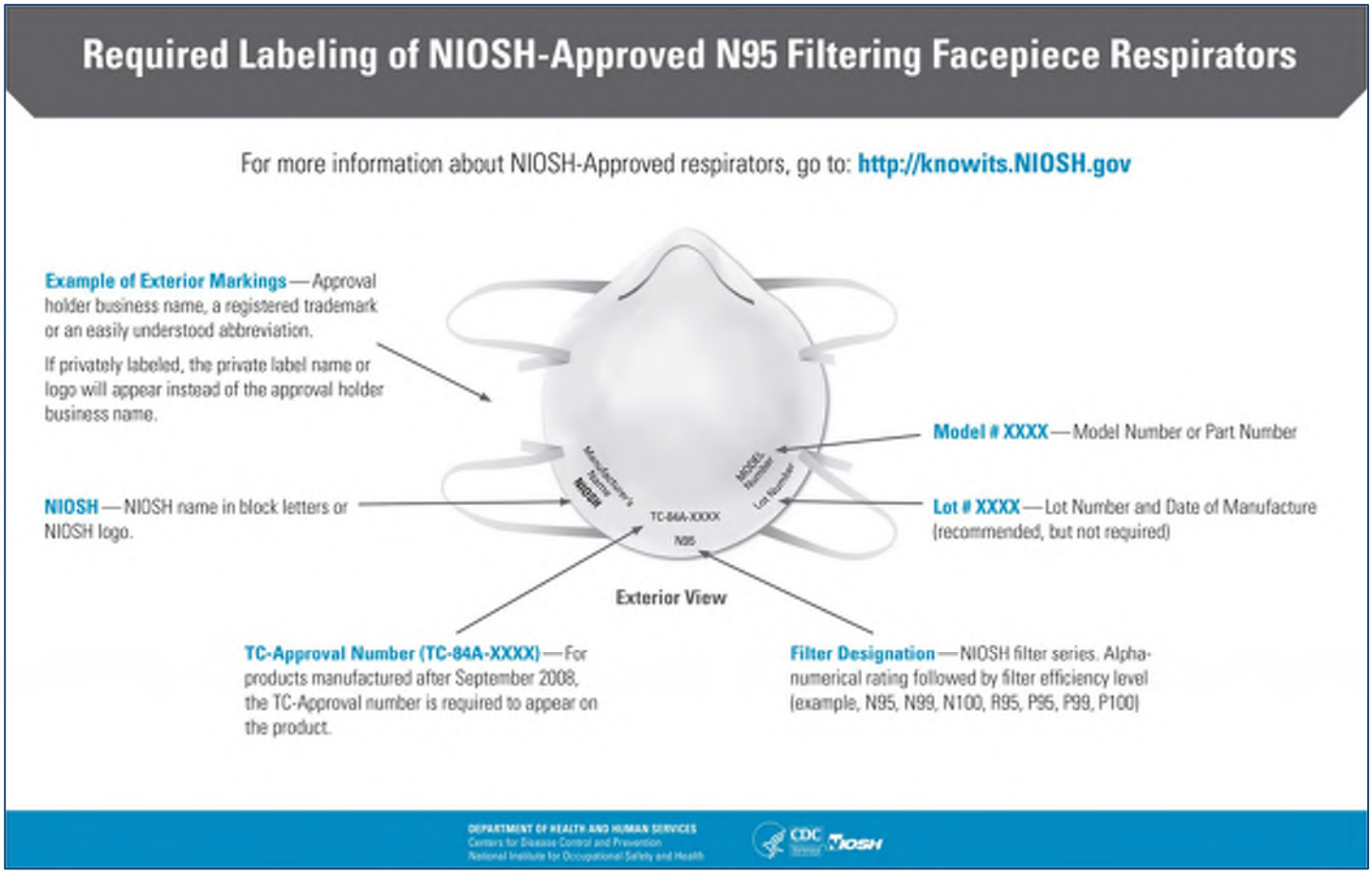


Figure 5 - Infographic from https://www.cdc.gov/niosh/npptl/pdfs/N95-Infographic-Mask-Labeling-508.pdf

Screening recommendation: Ultimately, it may be desirable to test a sample of received respirators to achieve high confidence that the respirators are capable of providing appropriate respiratory protection. The recommendation is to test the particulate filter efficiency per NIOSH procedure TEB-APR-STP-0059. Poor filter penetration results (<95%) may indicate a counterfeit product [2].

NPPTL Respirator Assessments

The National Personal Protective Technology Laboratory (NPPTL) is completing assessments of international respirators that are not currently NIOSH-approved. The evaluated respirators were only tested to assess the particulate filter efficiency per the NIOSH Standard Test Procedure TEB-APR-STP-0059. Please refer to the CDC website for the latest information:
https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html (refer to Appendix C for translation)

As stated on the CDC website, "The results of these tests are for the sample tested and may or may not be representative of a larger lot or population of similar respirators. The results of any filter penetration test can only be used to provide a check of the product's filter efficiency. No conclusions can be made regarding equivalency to N95 products that are NIOSH approved [2]."

3) Extended Use and Reuse Guidance

N95 respirators intended for single-use (disposable) are essential PPE that are in short supply. Two strategies that are being used to ease this critical shortage are 1) extended use (wearing the N95 for more hours at a time) and 2) reuse (donning and doffing the same respirator multiple times). It is important to evaluate the potential risks and benefits when considering either of these strategies [7].

Extended Use

Extended use involves continued use of the respirator for up to several hours. As N95 respirators are designed to function for days to weeks at airflow rates consistent with breathing, the protection effectiveness should be able to persist as long as the fit / seal remains tight [7].

Reuse

Reuse involves doffing and donning the respirator several times instead of disposing of the respirator after a single use. There are several single-use N95 decontamination strategies that are showing promise, including [8]:

- Moist heat (refer to https://www.n95decon.org/heat for the latest guidance)
- Vaporous hydrogen peroxide (refer to https://www.n95decon.org/hydrogen-peroxide for the latest guidance)
- Ultraviolet germicidal irradiation (refer to https://www.n95decon.org/uvc for the latest guidance)
- Time (refer to https://www.n95decon.org/time for the latest guidance)

The manufacturer should be consulted regarding the potential impact of the above method(s) before deciding on the use of any decontamination strategy [1].

Risks

The risks associated with extended use and reuse strategies to conserve N95 supplies include the following [7]:

- Discomfort (associated with extended use): The heat and increased breathing effort associated with wearing the respirator may become intolerable over long periods of time. In addition, the face-mask interface may become sore or bruised due to the sustained tight fit.
- Loss of fit (associated with extended use or reuse): The metal nose clip and/or elastic bands are not designed to be more durable than necessary for a single-use application. If the metal nose clip or elastic bands deteriorate or fail, achieving a proper fit may be difficult.
- Loss of filtration effectiveness (associated with decontamination for reuse): Decontamination procedures may potentially compromise the filtering capabilities of the N95.
- Infection spread (associated with extended use and reuse): Contaminated N95 respirators may spread infection during use, doffing, or donning (in the case of reuse).

Appendix A – Additional Tips for Spotting Counterfeit Respirators

https://www.cdc.gov/niosh/npptl/usernotices/AdditionalTips.html

[to be translated]

Additional Tips for Spotting Counterfeit Respirators

Updated April 21, 2020

Before buying large quantities of respirators from third party market places or unfamiliar websites, look for the following possible warning signs:

Third-party marketplaces

- If a listing claims to be "legitimate" and "genuine," it likely is not.
- Examine transactions history and feedback if possible
  - On auction sites or third-party distribution networks, most have a link to the seller of the item and their past sales. This is where buyers have the option to leave feedback regarding the experience with the seller such as if the buyer received the item as advertised, if they received it in reasonable amount of time, and if the buyer was unhappy with the product. Many reviewers will report if a product didn't work or if it was cheap in construction.
- Are there fluctuations of items traded over time (high or low periods of transaction?)
  - Is the seller marketing the same products over time, or are they primarily selling trendy items? Legitimate businesses and distributors typically sell what they know and stay consistent with their stock over time. A buyer should be able to discover this by looking into a businesses' other products. Buyers should also be able to gain insight to sellers on big online platforms (reviews of the seller).
- Are there price deviations and fluctuations (Is it too good to be true?)
- Look at the quantity a buyer has in stock.
  - During a time of shortage, advertising "unlimited stock" could be an indication that the respirator is not approved.
- Does the seller break marketplace policy and hide their contact information within images to circumvent filters.
  - Typical third-party marketplaces require interactions between seller and buyer to occur within an on-site messaging system. Sellers should not try to circumvent this system to display personal contact information.

On websites – look at the big picture

- Is the primary contact email address connected to the website or is it a free email account?
  - Using a free email service may suggest the seller is not committed to the domain
- Look for bad grammar, typos, and other errors.
- Watch for cookie-cutter websites, where the sellers interchange several websites, making mistakes:
  - Mixing up names/logos
  - Leaving the site partially unfinished with dummy text
  - Blank pages
  - A nonsense privacy policy page and/or broken links.
  - Domain squatting type activity (misspell the domain).

Appendix B – Counterfeit Respirators / Misrepresentation of NIOSH-Approval

https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

[to be translated]

Counterfeit Respirators / Misrepresentation of NIOSH-Approval

Updated May 18, 2020

Counterfeit respirators are products that are falsely marketed and sold as being NIOSH-approved and may not be capable of providing appropriate respiratory protection to workers.
When NIOSH becomes aware of counterfeit respirators or those misrepresenting NIOSH approval on the market, we will post them here to alert users, purchasers, and manufacturers.

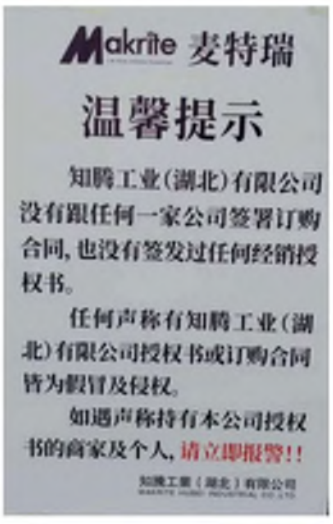
How to identify a NIOSH-approved respirator:

NIOSH-approved respirators have an approval label on or within the packaging of the respirator (i.e. on the box itself and/or within the users' instructions). Additionally, an abbreviated approval is on the FFR itself. You can verify the 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 the following designations: N95, N99, N100, R95, R99, R100, P95, P99, P100.

Signs that a respirator may be counterfeit:

- 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)
- Claims for the of approval for children (NIOSH does not approve any type of respiratory protection for children)
- Filtering facepiece respirator has ear loops instead of headbands

Additional Tips for Spotting Counterfeit Respirators Before You Buy



Translation of letter: "Makrite Hubei Industrial Co., Ltd has not signed any purchase contracts or agreement with any company or issued any distribution authorization. Anyone claiming that they have authorization or a purchase contract with Makrite Hubei Industrial Co., Ltd is forgery and infringement. In case of any business or individual claiming to have the authorization letter or certification from Makrite Hubei Industrial Co., Ltd, please report to the police immediately."

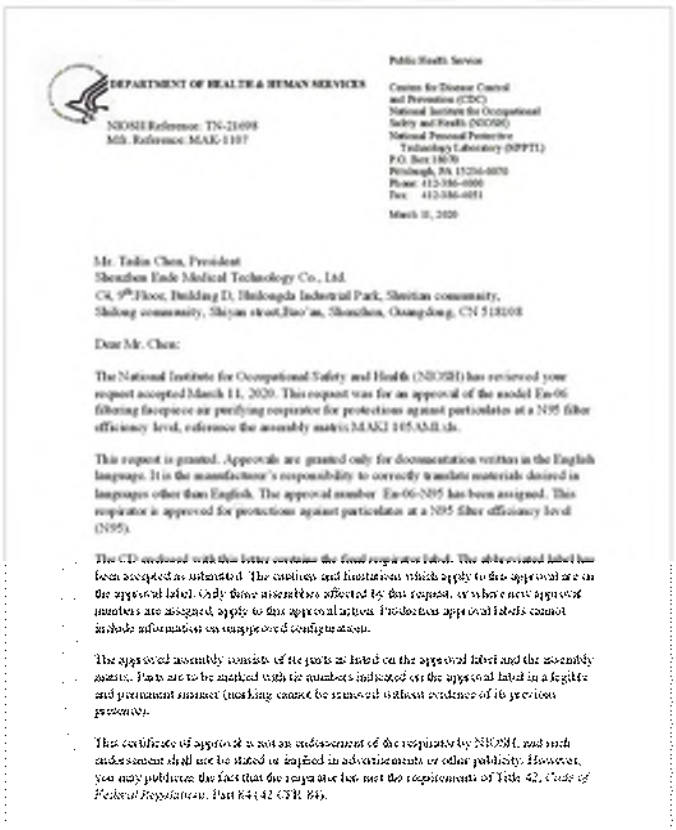
Makrite Hubei Industrial Co., Ltd, a subsidiary of NIOSH approval holder Makrite Industries Inc., issued a notice to alert customers of a product that is potentially being manufactured without the permission of Makrite and may be misrepresented as NIOSH approved. (5/15/2020)

Updated June 2, 2020

This is an example of a misrepresentation of a NIOSH-approved product. Products made by Jiangyin Chang-hung Industrial or labeled GRANDE are NOT NIOSH approved. The numbers listed on the packaging, TC-84A-4503, -84A-4639, -84A-4643, and -84A-4646, are not valid NIOSH approval numbers. (5/14/2020)

These are two examples of respirators being misrepresented as NIOSH approved on www.covidness.net. The SEKURA-321 is listed as NIOSH approved with approval number TC-84A-6660. Although this is a valid NIOSH approval number issued to Makrite, the website is selling a counterfeit respirator and using Makrite's approval number without their permission. The second example is called MIUTON. It is being misrepresented as NIOSH certified, but is NOT NIOSH approved. (5/13/2020)

This is an example of a counterfeit respirator using Shanghai Dasheng Health Products Manufacture Co. Ltd's (SDH) NIOSH approval number, TC 84A-4335, without their permission. SOUND is not a NIOSH approval holder or a private label holder. (4/28/2020)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-6000
Fax: 412-386-6951

NIOSH Reference: TN-21698
Mfr. Reference: MAK-1107

March 11, 2020

Mr. Tadin Chen, President
Shenzhen Ende Medical Technology Co., Ltd.
C6, 9th Floor, Building D, Huilongda Industrial Park, Shuitian community,
Shilong community, Shijan street,Bao'an, Shenzhen, Guangdong, CN 518108

Dear Mr. Chen:

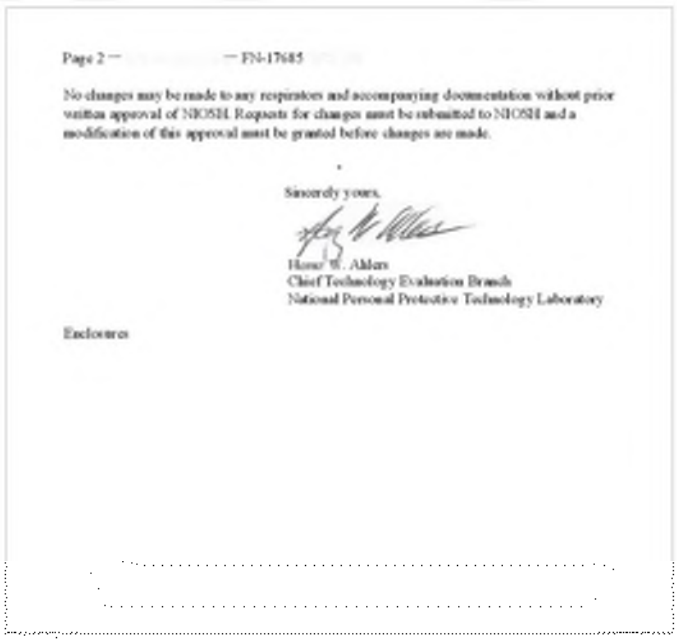
The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted March 11, 2020. This request was for an approval of the model En-06 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference the assembly matrix MAKI 105.A.B.1.ds.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. The approval number En-06-N95 has been assigned. This respirator is approved for protections against particulates at a N95 filter efficiency level (N95).

The CD enclosed with this letter contains the final respirator label. The abbreviated label has been accepted as submitted. The conditions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval actions. Previous approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that the respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).



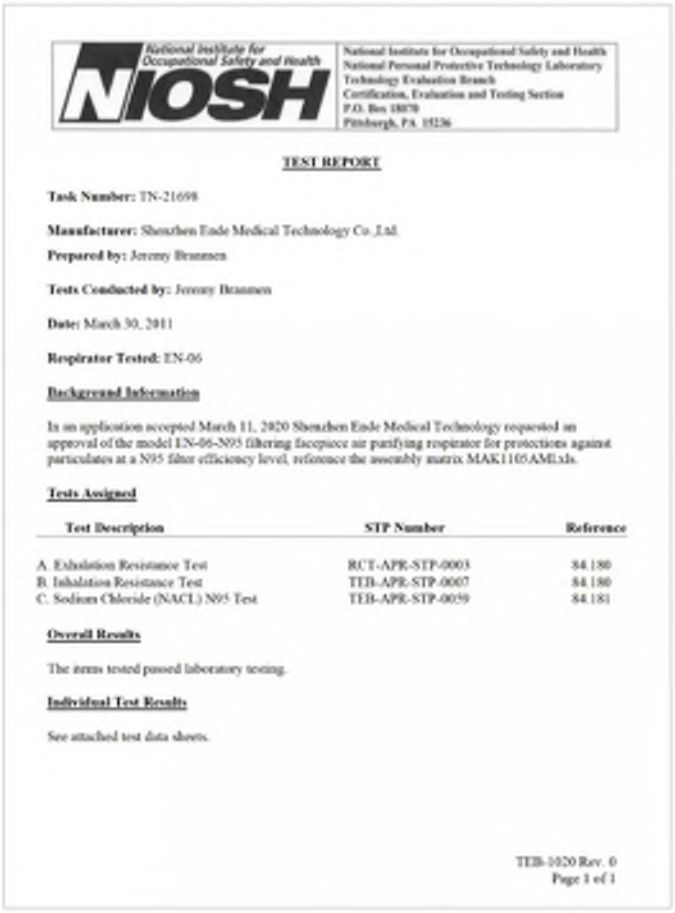
Page 2 — FN-17685

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely yours,

Heinz W. Ahlers
Chief Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures



National Institute for Occupational Safety and Health
NIOSH
National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Technology Evaluation Branch
Certification, Evaluation and Testing Section
P.O. Box 18070
Pittsburgh, PA 15236

TEST REPORT

Task Number: TN-21698

Manufacturer: Shenzhen Ende Medical Technology Co.,Ltd.

Prepared by: Jeremy Brannen

Tests Conducted by: Jeremy Brannen

Date: March 30, 2011

Respirator Tested: EN-06

Background Information

In an application accepted March 11, 2020 Shenzhen Ende Medical Technology requested an approval of the model EN-06-N95 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference the assembly matrix MAK1105AML.xls.

Tests Assigned

Test Description	STP Number	Reference
A. Exhalation Resistance Test	RCT-APR-STP-0003	84.180
B. Inhalation Resistance Test	TEB-APR-STP-0007	84.180
C. Sodium Chloride (NACL) N95 Test	TEB-APR-STP-0059	84.181

Overall Results

The items tested passed laboratory testing.

Individual Test Results

See attached test data sheets.

TEB-1020 Rev. 0
Page 1 of 1

NIOSH did not issue this letter and test report to Shenzhen Ende Medical Technology Co., Ltd. Although they appear to be from NIOSH, these documents have been altered and the information contained has been falsified. **Shenzhen Ende Medical Technology Co., Ltd. is NOT a NIOSH approval holder.** Any N95 filtering facepiece respirators from Shenzhen Ende claiming to be NIOSH-approved or accompanied by these documents are **NOT NIOSH approved.** (4/27/2020)

These are examples of counterfeit respirators using Shanghai Dasheng Health Products Manufacture Co. Ltd's (SDH) NIOSH approval numbers without their permission. These models include, but may not be limited to, models DTC3X (marked as TC-84A-4329), DTC3W (marked as TC-84A-4335), DTC3B (marked as TC-84A-4336), DTC3Z (marked as TC-84A-8150), and Raxwell RX9501P. Note that any SDH respirators with ear loops are **NOT** NIOSH approved. (4/17/2020)

This is an example of a misrepresentation of a NIOSH-approval. G & F Products is not a NIOSH approval holder or a private label holder. (4/9/2020)

Any respirators being sold as Maskin are no longer NIOSH approved. They are counterfeit or they are no longer compliant to the NIOSH approval. (4/9/2020)

This is an example of a counterfeit respirator. Medicos is selling an N95 respirator using the Moldex approval number and label without Moldex's permission. Medicos is not a NIOSH approval holder or private label holder. (3/12/2020)

This is an example of a misrepresentation of the NIOSH-approval. Yark is not a NIOSH approval holder or a private label holder. Additionally, respirators from the box include the CE (European) approval mark and NIOSH N95. This is not an acceptable format for a NIOSH-approved respirator. (3/5/2020)

RESPIRATOR USERS NOTICE

The Guangzhou Weini Technology & Development Co., Ltd. (GWT) respirator with model number K320 is not NIOSH-approved. GWT respirator approvals were rescinded in 2009. Please refer to our user notice for additional information. GWT respirators bearing any NIOSH approval number listed on the user notice is **NOT** NIOSH-approved. (2/10/2020)

There are no markings on the face of the respirator. (11/6/2019)

NIOSH does not approve any type of respiratory protection for kids. (11/6/2019)

There are no markings on the face of the respirator. (11/6/2019)

Updated June 2, 2020

This product is not NIOSH-approved. Look at the markings on the front. The logo is wrong, there is no approval number (TC-84A-xxxx). (11/6/2019)

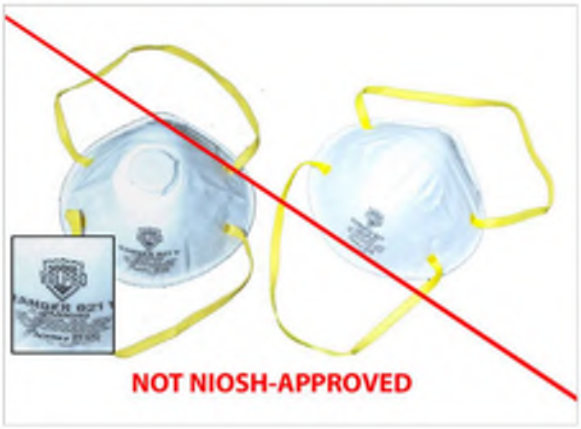
This product is not NOSH approved. No NIOSH logo or approval number on the face of the product. (11/6/2019)

This product is not NOSH approved. No NIOSH logo or approval number on the face of the product. (11/6/2019)

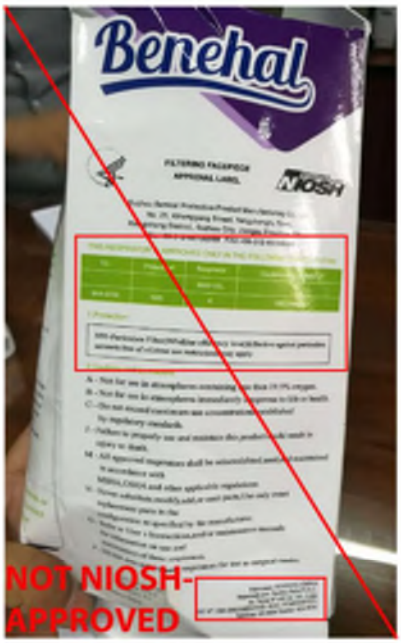
Images here are examples of counterfeit respirators. These respirators are being sold as if they are NIOSH-approved even though the manufacturer, Anhui Tongcheng YaGe Health Materials, Co., Ltd, is not listed as a NIOSH approval holder or a private label holder. (10/23/2019)

These are **examples of misrepresentation of the NIOSH-approval**. PitBull Safety Products is not a NIOSH approval holder. (10/07/2019)

This is an **example of misrepresentation of the NIOSH-approval**. Vogmask® is not a NIOSH approval holder. **This wording is misleading and not accurate:** ~~*With premium technologies and designs for best particle filtering results, our NIOSH certified Vogmask® is a reusable superior everyday face mask that protects one from dust, fine particulate matters (PM), pollen, air pollution, such as smog and smoke ... from https://www.vogmask.ca/*~~ (10/07/19)



This is an **example of two counterfeit respirators.** Valpro Safety is selling the Ranger 821 and Ranger 821V respirators using the 3M approval number (TC-84A-007) and label without 3M's permission. (6/19/19)

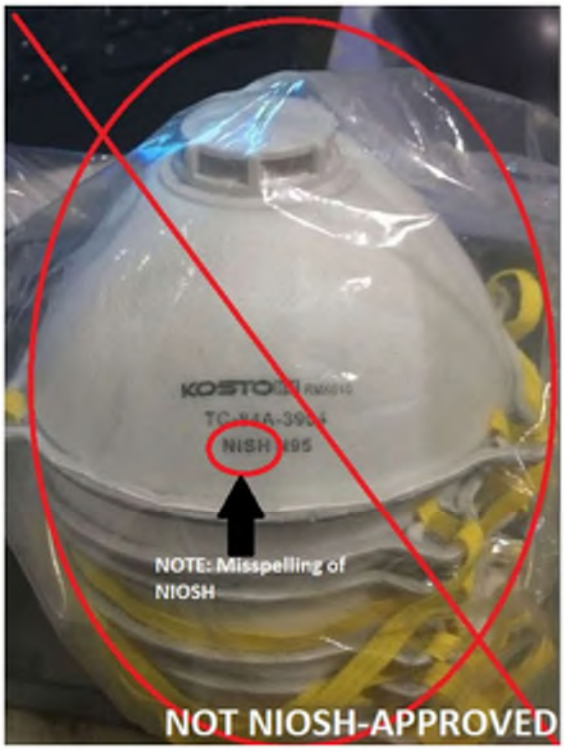


This is an **example of a counterfeit respirator**. Pacifico Salud SAC is selling units using the Suzhou Sanical Protection (SSP) approval number (TC-84A-6766) and label without SSP's permission. Additionally, there are two errors on the respirator package. The first error is that they claim the N95 respirator is 96% efficient. The second error is located in the bottom right corner of the package where is states the respirator is manufactured by Benehal China, who is not a NIOSH approval holder. (1/4/2019)

This counterfeit respirator, NT-V2 Nano Bi-Directional respirator, is being advertised as a NIOSH-approved, using a NIOSH approval number. The TC number (TC 84A-0427) belongs to a 3M full facepiece respirator with cartridges and was used without 3M's permission. Additionally, this counterfeit respirator was *not* manufactured by Pasture Pharma.

This respirator is being sold as if it is NIOSH-approved, even though the manufacturer, FitSeal, is not listed as a NIOSH approval holder or a private label holder. (2/19/2019)

This is an **example of misrepresentation of the NIOSH-approval**. All approvals for Wein Products (WPI) were rescinded in 2011. However, the manufacturer's website continues to state the ViraMask N99ESC is certified by NIOSH. View the user notice announcing the rescission.



This is an **example of a counterfeit N95 Respirator** that was brought to NIOSH's attention. While the TC number and private label holder are valid, this unapproved unit can be identified by the misspelling of NIOSH on the front of the respirator.

These are **examples of counterfeit respirators.** These respirators are being sold as if they are NIOSH-approved even though the manufacturer, Zubi-Ola, is not listed as a NIOSH approval holder or a private label holder.

Appendix C – International Assessment Results – Not NIOSH-Approved

https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html

[to be translated]

NPPTL Respirator Assessments to Support the COVID-19 Response

Updated May 22, 2020

International Assessment Results – Not NIOSH-approved

NPPTL has completed International Assessments for the products listed below.

NPPTL makes no representation as to the authenticity of the samples received and assessed. As part of its standard respirator approval process for NIOSH-approved respirators, NPPTL conducts a comprehensive quality assurance review of the quality process and manufacturing site. None of these reviews were conducted during this limited assessment. Further, no certificates of approval were provided with the samples. Therefore, validation of the claims that the product meets a particular international standard cannot be made.

For each model listed, ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. Only particulate filter efficiency was assessed. The results of these tests are for the sample tested and may or may not be representative of a larger lot or population of similar respirators. The results of any filter penetration test can only be used to provide a check of the product's filter efficiency. No conclusions can be made regarding equivalency to N95 products that are NIOSH approved.

No certificates of approval were provided with the samples received. Therefore, the authenticity of the claims, that the product meets a particular international standard, cannot be validated.

These assessments are not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process.

These assessments were developed as an assessment of the filter efficiency for those respirators represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers and other workers due to the respirator shortage associated with COVID-19.

Most of these products have an ear loop design. NIOSH-approved N95s typically have head bands. 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.

These results are not to be used by manufacturers, distributors, suppliers, and importers to make claims about their products and/or to influence purchasers.

NIOSH has been informed that many legitimate manufacturers in China have been counterfeited. In such cases, NIOSH has no way of verifying which products are counterfeit and which are authentic. While the manufacturer listed in the table is shown as the manufacturer of the product evaluated, NIOSH has been informed that some of these are actually counterfeit products. Some products with legitimate manufacturer names, showing poor filter penetration results (<95%), are counterfeit products. A number of manufacturers have also informed NIOSH that they did not produce the products associated with their name. NIOSH urges purchasers of masks and respirators that may have questions about the authenticity of these products to contact directly the manufacturers and others in the supply chain as needed to verify that they are obtaining legitimate products.

Manufacturers denoted with an asterisk (*) have informed NIOSH that the product evaluated was not manufactured by them, and should be considered as counterfeit and a misuse of their company name.

Refer to the website to view the latest list of results under the following table headings:

Manufacturer	Model Number/Product Line	International Standard	Filtration Efficiency (%)		Test Report
			Maximum	Minimum	

Appendix D – 3M Qualitative Fit Test [to be translated]

https://multimedia.3m.com/mws/media/1658130O/quick-reference-guidequalitative-fit-testing.pdf

3M Science. Applied to Life.™

Quick Reference Guide: Qualitative Fit Testing

3M™ FT-10 (sweet) and 3M™ FT-30 (bitter) fit test kits are suitable for disposable respirators, half facepiece fitted with particulate filters, and full facepieces fitted with particulate filters.[1]

! Wearers must be clean-shaven to get a proper fit with a respirator.

! Please note, in order to carry out a full fit test, all the steps detailed below must be followed (Parts 1 & 2).

Part 1 - Sensitivity Testing (The "Taste Test")

1. Add 1/2 teaspoon of sensitivity solution (in red labeled bottle) into the sensitivity nebulizer (marked in red). Visually confirm that the nebulizer produces a cloud of aerosol when the bulb is squeezed.
2. Place test hood on participant. A respirator should not be worn during the sensitivity test.
3. Ask the participant to breathe through their mouth with their tongue slightly extended and ask them to indicate immediately when they taste the solution.
4. Squeezing the bulb completely and aiming the nebulizer to the side rather than directly at the subject, squeeze solution into the hood and count the number of squeezes it takes for the solution to be tasted.
5. If desired, participant may drink some water.

! **Stop the test if solution is not tasted after 30 squeezes. Try an alternative solution from below.**

Sweet taste	3M-FT11 (sensitivity solution) 3M-FT12 (test solution)
Bitter taste	3M-FT31 (sensitivity solution) 3M-FT32 (test solution)

[1]Quantitative fit testing must be used when an assigned protection factor higher than 10 is needed for a full facepiece used in negative pressure mode, per 29 CFR 1910.134

Part 2 - Fit Testing

1. Add 1/2 teaspoon of test solution **(in black labeled bottle)** into the test nebulizer **(marked in black)**. Visually confirm that the nebulizer produces a cloud of aerosol when the bulb is squeezed.
2. Don the respirator and make sure respirator is fitted correctly. Refer to the 3M fitting instructions or poster for correct procedure. After the respirator is correctly donned, wait five minutes before beginning the next step.
3. Place test hood on participant.

Number of Squeezes Needed in Part 1	Number of Squeezes for Initial Dose	Number of Squeezes for a Replenishing Dose Every 30 Seconds
1-10	10	5
11-20	20	10
21-30	30	15

4. Introduce solution in an initial dose and start the exercises. Add a replenishing dose after every 30 second per the table below.
5. After the initial dose, ask the participant to carry out the 7 exercises shown in turn for 1 minute each and indicate immediately if solution is tasted. Remember to add a replenishing dose every 30 seconds. **Throughout the test, remind the participant to breathe through their mouth and visually confirm that the nebulizer is not clogged.**
6. Record all results.
   If solution is not tasted after all 7 exercises. they have passed the test with that specific respirator. **If solution is tasted, stop the test, rinse mouth, face, and hands, refit respirator and restart at Part 1 - Sensitivity Testing.**
   If solution is still tasted on the second attempt, stop the test, rinse hands, mouth, and face, and consider trying an alternative 3M respirator.
7. Discard all unused solution.

7 Exercises

This product is part of a system that helps reduce exposures to certain airborne contaminants. Before use, the wearer must read and understand these User Instructions. Follow all local regulations. In the U.S., a written respiratory protection program must be implemented meeting all the requirements of 29 CFR 1910.134, including training, fit testing and medical evaluation. In Canada, CSA standard Z94.4 requirements must be met and/or requirements of the applicable jurisdiction, as appropriate. Misuse may result in injury, sickness or death. For correct use, consult supervisor and User Instructions, or call 3M Technical Service in USA at 1-800-243-4630 and in Canada at 1-800-267-4414.

Personal Safety Division
3M Center, Building 235-2W-70
St. Paul, MN 55144-1000

3M PSD products are occupational use only.

In United States of America
Technical Service: 1-800-243-4630
Customer Service: 1-800-328-1667
3M.com/workersafety

In Canada
Technical Service: 1-800-267-4414
Customer Service: 1-800-364-3577
3M.ca/Safety

For a demonstration video, visit the link below.

go.3M.com/Fit

References

[1] CDC, "Decontamination and Reuse of Filtering Facepiece Respirators," 29 April 2020. [Online]. Available: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html. [Accessed 28 May 2020].

[2] NPPTL, "NPPTL Respirator Assessment to Support the COVID-19 Response," 18 May 2020. [Online]. Available: https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html. [Accessed 28 May 2020].

[3] CDC, "Filtering out Confusion: Frequently Asked Questions about Respiratory Protection," 2018. [Online]. Available: https://www.cdc.gov/niosh/docs/2018-129/pdfs/2018-129.pdf?id=10.26616/NIOSHPUB2018129. [Accessed 28 May 2020].

[4] CDC, "Personal Protective Equipment: Questions and Answers," 14 March 2020. [Online]. Available: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html. [Accessed 28 May 2020].

[5] FDA, "Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex," 24 August 2018. [Online]. Available: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-labeling-medical-products-inform-users-product-or-product-container-not-made-natural. [Accessed 28 May 2020].

[6] S. Rengasamy, G. Niezgoda and R. Shaffer, "Flammability of Respirators and other Head and Facial Personal Protective Equipment," *Journal of the International Society for Respiratory Protection,* vol. 35, no. 1, pp. 1-13, 2018.

[7] ECRI, "Safety of Extended Use and Reuse of N95 Respirators," 13 May 2020. [Online]. Available: https://assets.ecri.org/PDF/COVID-19-Resource-Center/COVID-19-Clinical-Care/COVID-ECRI-N95-Respirators-updated-5.pdf. [Accessed 28 May 2020].

[8] 2020. [Online]. Available: https://www.n95decon.org/. [Accessed 28 May 2020].

[9] NPPTL, "Additional Tips for Spotting Counterfeit Respirators," 21 April 2020. [Online]. Available: https://www.cdc.gov/niosh/npptl/usernotices/AdditionalTips.html. [Accessed 28 May 2020].

[10] NPPTL, "Counterfeit Respirators / Misrepresentation of NIOSH-Approval," 18 May 2020. [Online]. Available: https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html. [Accessed 28 May 2020].

[11] ECRI, "N95 Masks: New Guidance for Addressing Shortages," 15 April 2020. [Online]. Available: https://www.ecri.org/landing-covid-19-medical-devices-respirator-masks. [Accessed 28 May 2020].

[12] FDA, "N95 Respirators and Surgical Masks (Face Masks)," 05 April 2020. [Online]. Available: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks. [Accessed 28 May 2020].

[13] M. a. K. C. J. D'Alessandro, "Proper N95 Respirator Use for Respiratory Protection Preparedness," 16 March 2020. [Online]. Available: https://blogs.cdc.gov/niosh-science-blog/2020/03/16/n95-preparedness/. [Accessed 28 May 2020].

[14] ECRI, "Safety of Extended Use and Reuse of N95 Respirators," 13 May 2020. [Online]. Available: https://assets.ecri.org/PDF/COVID-19-Resource-Center/COVID-19-Clinical-Care/COVID-ECRI-N95-Respirators-updated-5.pdf.