



June 6, 2020

To: Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators;
Health Care Personnel;
Hospital Purchasing Departments and Distributors;
Importers and Commercial Wholesalers; and
Any Other Applicable Stakeholders.

Dear Stakeholder:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the Coronavirus Disease 2019 (COVID-19) outbreak, subject to the terms of any authorization issued under that Section.¹

On March 24, 2020, in response to this public health emergency and concerns about filtering facepiece respirator (FFR or respirator) availability, FDA concluded based on the totality of scientific evidence available that certain imported disposable FFRs that are not approved by the Center for Disease Control and Prevention's National Institute of Occupational Safety and Health (NIOSH) meet the criteria for issuance under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3).

On March 28, 2020, to further address availability concerns with disposable FFRs, FDA determined it was necessary to reissue the March 24, 2020 letter in order to amend the Scope of Authorization (Section II) to additionally authorize the use of authorized respirators that have been decontaminated pursuant to the terms and conditions of an authorized decontamination

¹ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 4, 2020). U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564 of the Federal, Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. March 2, 2020.

system.² FDA reissued the March 24, 2020 letter on March 28th, 2020 in its entirety with the revisions³ incorporated to authorize the emergency use of:

- 1) Authorized respirators listed in Exhibit 1 for use in healthcare settings by healthcare personnel (HCP)⁴ when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak; and,
- 2) Authorized respirators listed in Exhibit 1 that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system for use in healthcare settings by HCP when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

On June 6, 2020, having concluded that revising this Emergency Use Authorization (EUA) is appropriate to protect the public health or safety under section 564(g)(2) of the Act (21 U.S.C. § 360bbb-3(g)(2)), FDA is reissuing the March 28, 2020 letter in its entirety with revisions to:

1. Revise the second criterion for eligibility to only authorize disposable FFRs that conform to Personal Protective Equipment (PPE) Directive 89/686/EEC (for those placed into distribution before April 21, 2019) or that conform to PPE Regulation (European Union (EU)) 2016/425 (for those placed into distribution after April 21, 2019), as evidenced by a CE mark;
2. Add a third criterion that authorizes disposable FFRs that are manufactured by entities that hold one or more NIOSH approvals, that have been verified by FDA, for FFRs, and that are produced by the NIOSH approval holder in accordance with the applicable standards of authorization in another country.
3. Revise the Scope of Authorization such that decontaminated respirators with exhalation valves are no longer in the scope of products authorized by this EUA.
4. Add Conditions of Authorization to require samples for testing when requested by FDA

² For purposes of this EUA, an “authorized decontamination system” means any decontamination system that has been issued an EUA. Authorized decontamination systems can be found on FDA’s Emergency Use Authorization webpage, available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.³ The March 28, 2020 revision to the March 24, 2020 letter revised the Scope of Authorization to include authorized respirators listed in Exhibit 1 that are decontaminated using an authorized decontamination system.

³ The March 28, 2020 revision to the March 24, 2020 letter revised the Scope of Authorization to include authorized respirators listed in Exhibit 1 that are decontaminated using an authorized decontamination system.

⁴ Healthcare personnel refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These healthcare personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).⁵ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

- and prevent distribution of shipments that fail testing
5. Add Conditions of Authorization regarding printed materials, advertising, and promotion under section 564(e)(4) of the Act.

Additional revisions for clarity have also been made in this letter and FDA has further revised the Scope of Authorization (Section II) to explain a process for removal from Exhibit 1.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the authorized respirators, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter for use in healthcare settings by HCP when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: [Strategies for Optimizing the Supply of N95 Respirators](#). This EUA does not permit use of authorized respirators by the general public.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of authorized respirators as described in the Scope of Authorization (Section II) of this letter for use in healthcare settings by HCP to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized respirators may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages, and that the known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages during COVID-19, outweigh the known and potential risks of such products; and
3. There is no adequate, approved, and available alternative to the emergency use of the certain respirators for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread.^{5,6}

II. Scope of Authorization

⁵ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

⁶ There are not sufficient quantities of FFRs that are both NIOSH-approved and meet FDA regulatory requirements to meet the needs of the U.S. healthcare system. These disposable respirators are an integral part of routine patient care. Providing HCP who are on the forefront of the COVID-19 response with FFRs consistent with the CDC's guidance and recommendations is necessary in order to reduce the risk of illness in HCPs and increase their willingness to provide care to affected patients or those suspected of having COVID-19.

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of respirators that meet the criteria for eligibility as described in this section for use in healthcare settings by HCP in accordance with CDC’s recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak. Non-valved authorized respirators that are decontaminated pursuant to an authorized or cleared decontamination system are also authorized as described below.

Respirators Eligible for Authorization under this EUA

Respirators meeting at least one of the criteria in the following three categories are authorized under this EUA and will be listed in Exhibit 1 pursuant to the procedure outlined below. The categories of eligibility are as follows:

- 1. Disposable FFRs that have been designed, evaluated, and validated to meet a given performance standard and have corresponding acceptable product classifications, as follows:**

Table 1:

Jurisdiction⁷	Performance Standard	Acceptable product classifications	Standards/ Guidance Documents	Protection Factor ≥ 10
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PFF3, PFF2	Fundacentro CDU 614.894	YES
Europe	EN 149-2001	FFP3, FFP2	EN 529:2005	YES
Japan	JMHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
Korea	KMOEL-2017-64	Special 1 st	KOSHA GUIDE H-82-2015	YES
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES

- 2. Disposable FFRs that conform to Personal Protective Equipment (PPE) Directive 89/686/EEC (for those placed into distribution before April 21, 2019) or that**

⁷ Canada is not listed because it allows self-declaration to NIOSH or equivalent standards.

conform to PPE Regulation (European Union (EU)) 2016/425 (for those placed into distribution after April 21, 2019), as evidenced by a CE mark,⁸ and the CE mark has been authenticated and verified by FDA.

- 3. Disposable FFRs that are manufactured by entities that hold one or more NIOSH approvals, that have been verified by FDA, for FFRs, and that are produced by the NIOSH approval holder in accordance with the applicable standards of authorization in another country.**

In order to be added to Exhibit 1 as an authorized respirator under this EUA, manufacturers and/or importers must send a request to FDA by email of their intent to import non-NIOSH approved disposable respirators that meet one of the above criteria. The manufacturer or importer should send a request to be added to Exhibit 1 under this EUA by email to FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov with the subject “Imports FFRs” and the following information, which will allow FDA to determine whether the disposable respirator meets the criteria to be added to Exhibit 1 as an authorized respirator under this EUA:

For respirators meeting criterion 1:

- Specify the manufacturer contact information (name, address, contact person, phone number, and email), model number(s), certificate from a conformity assessment body (including the certificate number and name of the conformity assessment body (if any)), certificate of conformity (if available), applicable performance standards that the product meets and evidence that the product meets the standard, and any applicable guidance documents;
- A copy of the product labeling⁹; and
- An estimate of the number of respirators you are planning to import during the public health emergency.

For respirators meeting criterion 2:

- Specify the manufacturer contact information (name, address, contact person, phone number, and email) and model number(s);
- CE mark as evidenced by the following from a competent notified body for PPE:
 - EU type examination certificate and evidence of production monitoring and/or control or of quality assurance of the production system, or
 - European Commission (EC) type examination certificate and evidence of production monitoring and/or control or of quality assurance of the production system;
- A copy of the product labeling¹⁰;

⁸ There was a transition period for the EU regulation. Between April 21, 2018 and April 21, 2019, conformance to either PPE Directive 89/686 or PPE Regulation (EU) 2016/425 is acceptable. The type-examination certificates and approval decisions issued under Directive 89/686/EEC, before April 21, 2019, remain valid until April 21, 2023 unless they expire before that date

⁹ Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.

¹⁰ Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.

- An estimate of the number of respirators you are planning to import during the public health emergency; and
- A list of authorized importer(s) including contact information (name, address, contact person, phone number, and email).

For respirators meeting criterion 3:

- The manufacturer contact information (name, address, contact person, phone number, and email), model number, and NIOSH approval numbers for your NIOSH approved respirator(s);
- The manufacturer name, address, model number, and a copy of the product labeling¹¹ for the respirator(s) you want added to Exhibit 1; and
- An estimate of the number of respirators you are planning to import during the public health emergency.

Once FDA receives the above information, and any additional information it needs to confirm authorization of the imported disposable respirator with eligibility under one or more of the criteria outlined above, FDA will notify the manufacturer of the inclusion of their authorized respirator(s) in Exhibit 1 under this EUA by replying to the manufacturer's or importer's email.

Authorized Respirators

A respirator that meets one of the criterion for eligibility defined above, when labeled as described in this letter, is authorized to be distributed to and used in healthcare settings by HCPs in accordance with CDC's recommendations under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

Additionally, authorized respirators that have been decontaminated using an authorized decontamination system, with the exception of authorized respirators with exhalation valves, remain authorized under this EUA to be reused in healthcare settings by HCP when used in accordance with the terms and conditions of the authorized or cleared decontamination system without the need for any action by the respirators' manufacturer, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

As with any EUA, authorized products are subject to surveillance and monitoring. Here, for example, respirators on Exhibit 1 are subject to random sampling and filtration efficiency performance testing upon importation into the United States.

FDA may remove a product that has been added to Exhibit 1 if FDA has reason to believe that the product no longer meets the Criteria for Issuance (Section I), or the Scope of Authorization (Section II). FDA will provide the manufacturer advance notice of such removal, and will be available to work with the manufacturer regarding the planned removal of the product(s) from

¹¹ Please note that respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.

Exhibit 1. A respirator that has been removed from Exhibit 1 will be included in a list maintained on FDA's EUA webpage.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized respirators when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized respirators may be effective at preventing HCP exposure to certain particulates to prevent disease spread, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and conclude that the authorized respirators, when used in healthcare settings to prevent HCP exposure to certain particulates to prevent disease spread (as described in the Scope of Authorization of this letter (Section II)), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized respirators under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the authorized respirators are authorized to be used in healthcare settings by HCP under the terms and conditions of this EUA. EUA amendments may be undertaken as needed with concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

III. Waiver of Certain FDA Requirements

I am waiving applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized respirators that are used in accordance with this EUA.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Manufacturers of Authorized Respirators

- A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. FDA will make this information available to the public on its EUA website at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe>. Manufacturers must notify FDA of any changes to this page.
- B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.
- C. Manufacturers of authorized respirators will notify the importer (if applicable) of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.
- D. Manufacturers of authorized respirators will have a process in place for reporting adverse events of which they become aware and send such reports to FDA.
- E. All descriptive printed material relating to the use of the authorized respirators in the United States shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.
- F. No descriptive printed matter relating to the use of the authorized respirators in the United States may represent or suggest that the product is safe or effective for the prevention of COVID-19.
- G. Manufacturers of authorized respirators will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- H. Manufacturers of authorized respirators that are decontaminated by an authorized decontamination system are not responsible for any additional conditions that may apply to the manufacturer and/or operator of the decontamination system, unless they are the same manufacturer.
- I. If requested by FDA, manufacturers of authorized respirators will submit new lots for testing by NIOSH or by another entity designated by FDA.

- J. The manufacturers of authorized respirators must not distribute any lot or shipment that fails testing.

Importers

- K. All descriptive printed material relating to the use of the authorized respirators shall be consistent with applicable [CDC recommendations](#) for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.
- L. No descriptive printed material relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.
- M. Importers of authorized respirators will notify manufacturers of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition J.
- N. Importers of authorized respirators will ensure that any records associated with this EUA are maintained until the end of this public health emergency.
- O. If requested by FDA, importers of authorized respirators will submit new lots for testing by NIOSH or by another entity designated by FDA.
- P. The importers of authorized respirators must not distribute any lot or shipment that fails testing.

Manufacturers and/or Operators of Authorized Decontamination Systems

- Q. Each manufacturer and/or operator of an authorized decontamination system for decontamination of authorized respirators must comply with the Conditions of Authorization and authorized labeling as set forth in the Letter of Authorization for the authorized decontamination system.

Conditions Related to Printed Materials, Advertising and Promotion

- R. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product, shall be consistent with the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- S. No descriptive printed matter, including advertising or promotional materials, relating to the use of your product, may represent or suggest that the authorized product is NIOSH-approved.

The emergency use of the authorized respirators as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/S/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures