COVID-19 | Healthcare Coalition

International Regulatory Standards and Comparisons for N95 Respirators

N95 Working Group Report

The COVID-19 Healthcare Coalition is a collaborative private-industry response to novel coronavirus. Our mission is to save lives by providing real-time learning to preserve healthcare delivery and protect populations. (https://c19hcc.org)

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Summary

Due to the shortage of N95 respirators in the U.S. during the COVID-19 pandemic, hospitals and healthcare workers are looking to international suppliers to supplement crucial personal protective equipment (PPE). Similar respirators to the gold standard N95 are available for import from many countries under different designations.

Many of these respirators carry the same quality and safety standards as the N95 respirators. Those standards are established by the National Institute for Occupational Safety and Health (NIOSH), which is part of the U.S. Centers for Disease Control and Prevention, in the U.S. Department of Health and Human Services. With these standards in mind, the Food and Drug Administration (FDA) has issued an *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) Guidance* for industry and FDA Staff.[1]

Respirator Options

FDA guidance for ordering and using respirators:

1: Use respirators approved/cleared or sterilized under a traditional 510K FDA Pathway

2: Use respirators recognized under an FDA Emergency Use Authorization (EUA), which include:

- NIOSH-approved air purifying respirators, including those beyond recommended shelf life (Issued March 2, clarified March 11 and March 28)
- Non-NIOSH approved disposable filtering facepiece respirators authorized under March 24 EUA (reissued March 28)
- Non-NIOSH approved disposable filtering facepiece respirators made in China approved under April 3 EUA, including steps to validate authenticity
- Reuse of 510K-cleared respirators with EUA-approved decontamination methodology

3: When the above options are not available, individual healthcare providers may improvise in the following ways:

- Use and distribution of improvised PPE when no FDA-cleared masks or respirators are available
- The FDA lifted certain restrictions on use of CDC-recommended respirators

[1] https://www.fda.gov/media/136449/download

- For the duration of the public health emergency, when FDA- cleared or NIOSH-approved N95 respirators are not available, FDA does not intend to object to the distribution (including importation) and use of respirators identified in the CDC recommendations without compliance with the following regulatory requirements:
  - Prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81
  - Registration and Listing requirements in 21 CFR 807
  - Quality System Regulation requirements in 21 CFR 820
  - Reports of corrections and removals in 21 CFR Part 806
  - Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20
- Note: Because the FDA cannot confirm the authenticity of the respirators described above, it recommends that importers take appropriate steps to verify the authenticity of the products they import.

Guidance by Country of Origin

The EUA[2] provides the required approvals for respirator usage if a respirator is produced and approved outside of the United States and is accompanied by a clarification document[3]. The initial EUA was effective March 24, 2020, and reissued on March 28, 2020.[4] The new authorization accepts PPE from the following countries, since these countries have similar standards to NIOSH:

- **Australia** (P3, P2)
- **Brazil** (PFF3, PFF2)
- **Europe** (FFP2, FFP3)
- **Japan** (DS/DL3, DS/DL2)
- **Korea** (Special 1st)
- **Mexico** (N100, P100, R100, N99, P99, R99, N95, P95, R95)

China. On April 3, 2020,[5] the March EUA was extended to include non-NIOSH-approved N95 respirators from China; these EUA-santioned respirators should be consider FDA-*authorized* and not FDA-*approved*. Only specific Chinese manufacturers[6] are covered under the new EUA for KN95s, so those should be prioritized. Other Chinese manufacturers of KN95 respirators are eligible for authorization if certain criteria are met, including evidence demonstrating that the mask is authentic and meets standards akin to N95 respirators. Although not required, manufacturers of KN95 respirators should be certified by a recognized standards governing body prior to use (such as NIOSH or GB (Guobiao)).

[2] https://www.fda.gov/media/135763/download
[3] https://www.fda.gov/media/136023/download
[4] https://www.fda.gov/media/136403/download
[5] https://www.fda.gov/media/136664/download
[6] https://www.fda.gov/media/136663/download

3M has released the following graphic, which compares the respirator standards across the international community.[7] This comparison was distributed in a Technical Bulletin released by 3M January 2020, Version 2.

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS (Japan JMHLW-Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO_2 clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.

Suppliers Not on the Approved List

Any supplier that is not on the authorized manufacturer list[7] must contact the FDA for sanctioning prior to importing their product. Per the guidance document established by the FDA, disposable non-NIOSH-approved respirators manufactured in China must meet *at least one* of the following criteria to qualify for the EUA and become FDA-authorized:

[7] https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf

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 other than China that can be authenticated and verified by FDA; or
3. It demonstrates acceptable performance to applicable testing standards as documented by test reports from a recognized independent test laboratory that can be verified by FDA.

The entirty of requirements are listed on the FDA website under the EUA guidelines.[8] To apply (and register), contact CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov with "Non-NIOSH-Approved Respirator" in the subject line and include:

A. General information, such as your contact information, name and place of business, email address, and contact information for a U.S. agent (if any), in addition to general information about the device such as the proprietary or brand name, model number, and marketing authorization in your country (or region).
B. A copy of the product labeling.
C. Whether the device currently has marketing authorization in another regulatory jurisdiction (including certification number, if available).
D. Whether the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes or an equivalent quality system and the manufacturer or importer has documentation of such.
E. Description of testing conducted on the device, including any standards met, such as liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate.

The FDA is ready and available to engage with importers to minimize disruptions during the importing process. The FDA established a special email inbox for industry representatives to quickly communicate with the agency and address questions or concerns[9]:

COVID19FDAIMPORTINQUIRIES@fda.hhs.gov,

[8] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities

[9] https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns#kn95