



## DLS Guidance for Public Sector –Selection of N95 Respirators During a Respirator Shortage 3-25-2020

Many healthcare tasks require the use of a NIOSH approved N95 respirator. Due to the current high demand of available respiratory protection, there is currently a shortage of N95 respirators. This guidance provides additional options that are temporarily available in response to the COVID-19 pandemic.

### Respirator Choices During Shortage

The CDC website provides the following options in this order:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html>  
and <https://www.cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html>

1. **Select a stronger respirator:** NIOSH approved N100, P100, R100 N99, P99, R99, N95, P95, R95, PAPR, tight-fitting, air-purifying, elastomeric respirator with P100 filter cartridges.
2. **Use an expired N95 that is tested to demonstrate it is still effective for healthcare delivery:**  
<https://www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html>
  - **Expired N95 that Passed:** 3M models 1860, 1870, 8210, 9010, 8000, Gerson 1730, Medline/Alpha, Protech NON27501 Moldex 1512,2201.
  - **Expired N95 that did NOT PASS:** Kimberly-Clark 46827(small); 46727(regular). Note that Kimberly Clark products that have not expired are still effective and can be worn.
3. **Use a respirator that is certified by a different country for emergency use by a Healthcare Provider.**
  - **FDA letter 3-24-2020** authorizing import and use of healthcare respirators manufactured in Australia, Brazil, EU, Korea, and Mexico. See table below.  
<https://www.fda.gov/media/136403/download>
  - **CDC website authorizing non-US certification** <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html>
  - **3M bulletin dated January 2020** showing that the NIOSH test method is equivalent to: Australia P3 and P2; China KN95; EU FFP3 FFP2; Japan DS/DL3 and DS/DL2; and Korea Special and 1<sup>st</sup>. The China respirator is not in the FDA letter.  
<https://multimedia.3m.com/mws/media/17915000/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf>

From FDA letter 03/24/2020 <https://www.fda.gov/media/136403/download>

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

<b>Table 1: Jurisdiction<sup>6</sup></b>	<b>Performance Standard</b>	<b>Acceptable product classifications</b>	<b>Standards/ Guidance Documents</b>	<b>Protection Factor <math>\geq 10</math></b>
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PPF3, PPF2	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 1st	KOSHA GUIDE H-82- 2015	YES
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES

Workplace Safety and Health Program for Public Employees

[www.mass.gov/dols/wshp](http://www.mass.gov/dols/wshp)

508-616-0461 and choose #1

[safepublicworkplacemailbox@mass.gov](mailto:safepublicworkplacemailbox@mass.gov)