

April 10, 2020

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. The subject line of this email should read "URL for FFR Made in China." FDA will make this information available to the public on its EUA website at https://www.fda.gov/medical-devices/emergency-situationsmedical-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.

Pictures:

N95 MASK 3-PLY MASK



S.S.I.



General Instructions for Putting on an N95 Respirator (Mask)

These instructions must be followed each time the N95 mask is worn.





Before accessing and putting on an N95 mask clean your hands.

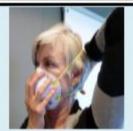
If wearing glasses, remove prior to putting on mask



Cup the mask in your hand with the metal nosepiece at your fingertips.

Allow the elastic headbands (straps) to hang freely below your hand.

3



Position the mask under your chin with the nosepiece up.

Pull the top strap over your head resting it high at the top back of your head.

Pull the bottom strap over your head and place it around the neck below the ears

4



Using **both** hands, mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece.

5



SEAL CHECK. The mask seal MUST be checked before each use. To check the fit, place both hands over the mask and exhale. If air leaks around your nose, adjust the nosepieces as described in step 4. If air leaks at the mask edges, adjust the straps back along the sides of your head. Check again.

If you cannot achieve proper fit, DO NOT enter the isolation room. Check with the nursing staff.

If wearing glasses, put them on