NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: UNKNOWN
Model Tested: 9001
Date Tested: June 17, 2020

These findings pertain to the UNKNOWN, model 9001. The packaging and labeling for this product indicate that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Thirty respirators were submitted for evaluation. Only ten respirators were requested, so, the decision was made to test twenty. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found here.

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 98.88% and 96.48%, respectively. All twenty respirators measured more than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product’s handling and exposures after leaving its manufacturer’s control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s 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.

This assessment is 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. This assessment was developed as an assessment of the filter efficiency for those respirator’s represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for Crisis Capacity Strategies (during known shortages).
**Test:** Modified TEB-APR-STP-0059  
**Date Tested:** June 17, 2020  
**Report Prepared:** June 17, 2020  
**Manufacturer:** UNKNOWN  
**Item Tested:** 9001  
**Country of Certification:** China (GB2626-2006)

<table>
<thead>
<tr>
<th>Filter</th>
<th>Flow Rate (LPM)</th>
<th>Initial Filter Resistance (mmH₂O)</th>
<th>Initial Percent Leakage (%)</th>
<th>Maximum Percent Leakage (%)</th>
<th>Filter Efficiency</th>
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- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.

Minimum Filter Efficiency: **96.49**  
Maximum Filter Efficiency: **98.63**
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**Minimum Filter Efficiency:** 96.48  **Maximum Filter Efficiency:** 98.88

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**Details:**

This KN95 particulate respirator has comfortable over materials and helps provide respiratory protection against certain airborne particles.

This KN95 respirator is designed to help provide respiratory protection for the wearer.

**Removal Instructions:**

Without touching the respirator, slowly lift both straps from your ears. Pull the mask away from your face. Store or discard according to your facility's infectious control policy. Dispose of used product in accordance with applicable regulations.

**Cautions and Limitations:**

1. Not for use in atmospheres containing less than 19.5 percent oxygen.
2. Not for use in atmospheres immediately dangerous to life or health.
3. Do not exceed maximum use concentrations established by regulatory standards.
4. Failure to properly use and maintain this product could result in injury or death.
5. Never substitute, modify, add, or omit parts. Use only exact replacement parts to the configuration as specified by the manufacturer.
6. Not for use with beard, or other facial hair or conditions that prevent a good seal between the skin and the sealing edge of the respirator.
7. This respirator was not designed to be used by children.

**Storage Conditions and Shelf Life:**

Before use, store respirators in the original packaging, away from contaminants, areas with direct sunlight, extreme temperatures, excessive moisture and damaging chemicals.

When stored in airpackaging changing between temperatures from -6°F to 22°C (0°F to 72°F) and not exceeding 80% RH, the composite product is valid for three years from the date of manufacture.

**Instruction:**

1. Wash hands before putting on a mask, before and after taking one off.
2. The nose clip part is insides, with the metallic strip upwards.
3. Position the mask against the skin first, hang the elastic straps of both ears to properly fit the mask firmly in place.
4. Then put on the mask to further adjust the fixing bar to a comfortable fit to your nose.
5. Place both hands on the nosepiece. Hold the nosepiece and smooth against your nose and face. Make sure the noseclip is properly secured and it does not pinch against your nose.
6. Remove the mask with both hands. Place both hands on the nosepiece. Hold the nosepiece and smooth against your nose and face. Make sure the noseclip is properly secured and it does not pinch against your nose.
7. Perform a Use Seal Check. To check the respirator on face, place both hands completely over the respirator and inhale. Make sure not to obstruct the position of the respirator. If a leak around the mask is detected, the nosepiece is described in step 5. If no leak around respirator edges, adjust position of mask and make certain respirator edges fit snugly against the face.

**IMPORTANT:**

Before use, wearer must read and understand these User Instructions. Keep these User Instructions for reference.
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