NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shenzhen Zhanhuwei Medical Supplies Co., Ltd.
Model Tested: N95
Date Tested: June 16, 2020

These findings pertain to the Shenzhen Zhanhuwei Medical Supplies Co., Ltd., model N95. The packaging for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-SP-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 99.85% and 99.22%, respectively. All ten 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).
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Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059
Date Tested: June 16, 2020
Report Prepared: June 16, 2020
Manufacturer: Shenzhen Zhanhuwei Medical Supplies Co., Ltd.
Item Tested: N95
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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</thead>
<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>13.8</td>
<td>0.34</td>
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<tr>
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<tr>
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</tr>
<tr>
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<td>18.4</td>
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<td>99.49</td>
</tr>
<tr>
<td>10</td>
<td>85</td>
<td>16.3</td>
<td>0.25</td>
<td>0.28</td>
<td>99.72</td>
</tr>
</tbody>
</table>


- 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.
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**1 PCS N95 PROTECTIVE MASK**

- Five layers of protection
- PM 2.5 Protective
- Comfortable touch
- Virus filtering

**CARE FOR HEALTH**

**Model:** N95  
**Executive standard:** GB2626-2006  
**Specifications:** approximately 160mm * 110mm  
**Storage period:** see the seal of the outer package  
**Method of use:** It can be used after opening the package  
**Product composition:** This product is made of cover Mask, cover Mask Clip and Respirator Strap  
**Storage way:** Pay attention to waterproof, high temperature, moisture and corrosion resistant gases; Keep out of direct sunlight, clean, dry and well ventilated  
**Product description:** Electrostatic filter material, unique shape design, well-matched nose clip and headband ensure close fitting with the face, in the same effect, breathing resistance is small, more comfortable to wear.  
**Application range:** This standard is applicable to the protection of all kinds of particulate matter self-absorption filter respiratory protective equipment, this standard is not applicable to the protection of harmful gases and steam respiratory protective equipment; this standard is not applicable to the hypoxia environment, underwater operations, escape and fire protection respiratory protective equipment.  
**Contraindication:** Use with caution for people who are allergic to non-woven materials.

**Brand:** YLW  
**Product name:** N95 Protective Mask  
**Applicable people:** General  
**Wearing style:** Earloop Mask  

**NON-Medicial**

Manufacturer: Shenzhen Zhanhuwei Medical Supplies Co. LTD  
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