NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangdong Nafei Industrial Holding Co., Ltd.
Model Tested: Efficient Nursing Protective Mask
Date Tested: May 1, 2020


Nine respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-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 10.50% and 1.10%, respectively. All nine respirators measured less 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:** May 1, 2020

**Report Prepared:** May 5, 2020

**Manufacturer:** Guangdong Nafei Industrial Holding Co., Ltd.

**Item Tested:** Efficient Nursing Protective Mask

**Country of Certification:** China (GB2626-2006, EN149:2001+A1:2009)

<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>
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<td>90.9</td>
<td>96.8</td>
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<td>1.7</td>
<td>91.4</td>
<td>96.5</td>
<td>3.50</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 1.10

Maximum Filter Efficiency: 10.50

- 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.
Product performance
The filtration efficiency of 0.075 μm NaCl or indoor aerosol particles, bacteria and viruses is not less than 95%. 2. The density shall not be lower than 150. 3. Filtration efficiency: KN95, in full compliance with GB2626-2006 industry standard. Bacterial filtration rate ≥95%. 4. According to the human face engineering design of 3D three-dimensional shape, to ensure the tightness and increase the breathing capacity of the mask, greatly improve the air permeability, make wearing more comfortable breathing.

Structural components
This product is made of polypropylene fusion-sprayed ultrafine fiber as filtration material and polypropylene spunbonded non-woven fabric as protective material. It is attached with nose clip, supporting material and variable plane one-cavity mask composed of upper and lower fixation.

Scope of application
It can be used in infectious diseases or emergencies to prevent the inhalation of airborne microorganisms and particulate matter. It can be used for the protection of ordinary people during the epidemic of infectious diseases, the protection of people with allergy to pollen inhalation, industry, decoration, outdoor cycling, etc.

Attention
1. This product is a disposable product and cannot be used repeatedly after washing.
2. Do not reuse after use in known or suspected contaminated areas.
3. This product is not suitable for protection against gaseous substances.
4. This mask is self-imbibition filter mask, which is not suitable for use in the environment with oxygen concentration lower than 18%.
5. Please store the product in a clean, ventilated and dry environment.

Production license: yueshan food and drug supervision equipment production no. 20200001
Manufacturer: Guangdong Nafei Industrial Holding Co., LTD
Origin: Shanwei, Guangdong
Warranty: 2 years
Specification: 1 piece/bag
Expiry date and batch number: see packaging
Made in China
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