NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Ningbo Kangqi Medical Supplies Co., Ltd.
Model Tested: KN95 Ear Face Mask
Date Tested: June 12, 2020

These findings pertain to the Ningbo Kangqi Medical Supplies Co., Ltd., KN95 Ear Face Mask. 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).

Ten respirators were submitted for evaluation. 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 85.50% and 53.10%, respectively. All ten 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:** June 12, 2020

**Report Prepared:** June 12, 2020

**Manufacturer:** Ningbo Kangqi Medical Supplies Co., Ltd.

**Item Tested:** KN95 Ear Face Mask

**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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<tbody>
<tr>
<td>1</td>
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<td>10.7</td>
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<td>43.0</td>
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<td>57.00</td>
</tr>
</tbody>
</table>

**Minimum Filter Efficiency:** 53.10  **Maximum Filter Efficiency:** 85.50

- 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.
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**USAGE**
Mask on mouth and nose, prevent inhalation or dust

**Wearing method**

1. Face the mask without nose AIP place the nose clip over the mask, place the mask on your face, put the mask on your chin.
2. Just pull the ear band to the outside of both ears and hang.
3. Put your fingers in the middle of the metal nose clip, press in while moving the fingertips to both sides along the nose clip, until the nose clip fully pressed into the shape of the bridge of the nose.
4. Put your hands on your face to check for face tightness.

**Product information**

- **PRODUCT NAME**: EAR FACE MASK
- **PRODUCT PERFORMANCE STRUCTURE AND COMPOSITION**: This product is made of multilayer thin fabric
- **PRODUCTION DATE**: Seal the outer package for batch number
- **SHELF LIFE**: 3 years
- **NOTE**: Patients with dyspnea or congenital heart should use it carefully

This product cannot be used as gas mask in toxic environment

Execution Standard: GB2626-2006

NINGBO KANGQI MEDICAL SUPPLIES CO., LTD
Zhejiang, China, 315400
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KN95 CIVIL MASK

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