Manufacturer: Dongguan Xianda Medical Equipment Co., Ltd.
Model Tested: KN95 Protective Mask
Date Tested: April 15, 2020

These findings pertain to the Dongguan Xianda Medical Equipment Co., Ltd., model KN95 Protective Mask. The labeling for these respirators indicate they meet GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator) and EN149:2001+A1:2009 (the European standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking).

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 35.00% and 24.10%, respectively. All ten respirators measured less than 95%.

While the above-listed product classifications have 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).
NPPTL COVID-19 Response: International Respirator Assessment

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059
Date Tested: April 15, 2020
Report Prepared: April 16, 2020

Manufacturer: Dongguan Xianda Medical Equipment Co., Ltd.
Item Tested: KN95 Protective Mask
Country of Certification: China (Chinese Standard GB2626, European Standard EN149)

<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>3.9</td>
<td>74.4</td>
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<td>5.0</td>
<td>72.9</td>
<td>74.0</td>
<td>26.0</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 24.10
Maximum Filter Efficiency: 35.00

- 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.
IMPORTANT:
1. When environmental pollutants seriously endanger health or the oxygen concentration is below 18%, do not use this product.
2. When the product is broken or the respiratory resistance increases, please replace it in time.
3. If the user feels discomfort, should be immediately examined and rest.

Go to the security area to rest and inspect if hard breath, dizziness, nausea or other distress occurs.

Product name: KN95 protective mask
Product grade: KN95
Product level: KN95
Specification: 2 PCS/bag
Storage conditions: Avoid direct sunlight, fire, and other pollution.
Use range: Daily use

Manufacturer: Dongguan Xinda Medical Equipment Co., Ltd.
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Telephone: 0769-81812339
NPPTL COVID-19 Response: International Respirator Assessment
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