NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Dongguan HuaGang Communication Technology Co., Ltd.
Model Tested: KN95 Disposable Face Mask
Date Tested: May 12, 2020

These findings pertain to the products labeled as Dongguan HuaGang Communication Technology Co., Ltd., KN95 Disposable Face Mask. The labeling for this product indicates that it meets 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 98.73% and 25.60%, respectively. Four respirators measured more than 95%. Six 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 12, 2020
Report Prepared: May 13, 2020
Manufacturer: Dongguan HuaGang Communication Technology Co., Ltd.
Item Tested: KN95 Disposable Face Mask


<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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>13.7</td>
<td>2.11</td>
<td>2.11</td>
<td>97.89</td>
</tr>
<tr>
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<td>85</td>
<td>9.9</td>
<td>49.7</td>
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<td>66.6</td>
<td>66.6</td>
<td>33.40</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 25.60 Maximum Filter Efficiency: 98.73

- 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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Thank you for choosing our face masks. They are designed to keep you and your family safe from dust, haze, droplets, etc. Lab tested and clinically proven in lowering the chance of exposure to airborne infections.

Product Description
- Efficient Filtration: Filtering at least 95% of dust, haze, droplets, etc.
- 4-layer Purification: Melt-blown Nonwovens, moderate thickness for particle absorption, double layered electrostatic filter, and highly efficient at filtering particles.
- Ergonomic Design: Comfortable to wear, low impedance filter material, with no odor.
- Securely Sealed: Adjustable metal strip ensures optimal sealing between the bridge of the nose and the mask.

Instructions
1. Unfold the mask and pull the bands outward on either end.
2. Position the mask on your face with adjustable metal strip facing up.
3. Place the bands around both ears.
4. Press down on the metal strip lightly to ensure the mask is securely sealed.

Warning
DO NOT use the mask in medical and surgical environments.
DO NOT use in an environment with oxygen concentration below 19.5%.
DO NOT use the mask if you have beard or other facial hair that has direct contact between your face and the edge of the mask.
DO NOT use the mask in toxic gas environment.

Note:
This mask may not eliminate the risk of all diseases and infections. This mask must be sealed properly, misuse can result in higher risk of sickness. For adult use only.

Keep storage area dry at room temperature and do not wash the mask with water.
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