NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangzhou Harley Commodity Co., Ltd.
Model Tested: L-103V KN95
Date Tested: May 1, 2020

These findings pertain to the Guangzhou Harley Commodity Co., Ltd., L-103V KN95. 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 observed was 99.49% and 99.02%, 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: May 1, 2020
Report Prepared: May 3, 2020
Manufacturer: Guangzhou Harley Commodity Co., Ltd.
Item Tested: L-103V KN95
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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>10.7</td>
<td>0.56</td>
<td>0.56</td>
<td>99.44</td>
</tr>
<tr>
<td>2</td>
<td>85</td>
<td>11.2</td>
<td>0.51</td>
<td>0.51</td>
<td>99.49</td>
</tr>
<tr>
<td>3</td>
<td>85</td>
<td>10.2</td>
<td>0.77</td>
<td>0.80</td>
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<td>4</td>
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<td>5</td>
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<td>10.5</td>
<td>0.56</td>
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<tr>
<td>6</td>
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<td>0.86</td>
<td>0.98</td>
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</tr>
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<td>7</td>
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<td>0.87</td>
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<td>8</td>
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<td>0.64</td>
<td>99.36</td>
</tr>
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<td>9</td>
<td>85</td>
<td>10.4</td>
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<td>0.61</td>
<td>99.39</td>
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<tr>
<td>10</td>
<td>85</td>
<td>9.9</td>
<td>0.71</td>
<td>0.73</td>
<td>99.27</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 99.02
Maximum Filter Efficiency: 99.49

- 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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Fitting Instructions:
1. Open the respirator with both hands.
2. Cup the respirator firmly against your face with the nosepiece on the bridge of your nose.
3. Stretch and pull the lower headband over the head and position below your ears. Stretch and pull the top headband on the back of your head above your ears.
4. Press plastic nosepiece to conform snugly around your nose.
5. Seal check
   1. To test the fit of a respirator without an exhalation valve cup both hands over the respirator and exhale sharply.
   2. To test the fit of a respirator with an exhalation valve, cup both hands over the mask and inhale sharply.
   A negative pressure should be detected inside the respirator.
   1. If air flow is felt in the nose area, re-adjust/tighten the nose clip.
   2. If air flow is felt around the edges of the respirator, reposition the respirator/head strap to achieve a better fit.
6. Change the mask immediately if breathing becomes difficult or mask becomes damaged or distorted.
7. Change the respirator if a proper face seal cannot be achieved.
8. Careful observance of these instructions is an important step in safe respirator use.

Warning:
High efficient against particulate aerosols free of oil. This respirator helps protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting disease or infection. Misuse may result in sickness or death.

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