NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Anhui Baishidun Protective Equipment Co., Ltd.
Model Tested: Baishidun FFP2
Date Tested: April 22, 2020


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.

A certificate of approval was not provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 53.00% and 46.10%, 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).
Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059
Date Tested: April 22, 2020
Report Prepared: April 22, 2020
Manufacturer: Anhui Baishidun Protective Equipment Co., Ltd.
Item Tested: Baishidun FFP2
Country of Certification: China (GB2626-2006 KN95) and Europe (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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>9.7</td>
<td>51.90</td>
<td>51.90</td>
<td>48.10</td>
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<td>10.5</td>
<td>48.18</td>
<td>48.18</td>
<td>51.82</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 46.10  Maximum Filter Efficiency: 53.00

- 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.

Pictures have been added to the end of this report.
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**Matters needing attention:**
1. This product is a one-time product and cannot be used after cleaning.
2. It is not recommended to wear the product if the air is not smooth, breathing is not smooth, or during sleep.
3. Do not throw this product after use to avoid secondary pollution, please use it up. Please fold it and put it in a special medical trash can.

**Instructions:**
**Wearing a mask with pictures**
1. Open the mask to keep the skin dry.
2. The white side faces the cotton cloth, and the bridge of the nose is above.
3. Hang the ears on both ears and adjust left and right to make the ears evenly stressed.
4. Adjust the size of the mask to cover the nose and mouth completely.
5. Use both hands to adjust the bridge of the nose to fit the bridge of the nose.
6. Smooth the mask an both sides to fit the face.

![Correct Operations Diagram]

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Product name: Self-Breathing Filtration Particle-Preventive Respirator
Production date: refer to the outer package
Product quantity: 20 pieces/box
Brand name: Baishidun
Manufacturer: Anhui Baishidun Protective Equipment Co., Ltd.
Address: East Ring Road, Qianshan Economic Development Zone, Anqing City, Anhui Province, China
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