NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shandong Haidike Medical Products Co., Ltd.
Model Tested: Medical Protective Mask - Folding Type
Date Tested: June 30, 2020

These findings pertain to the Shandong Haidike Medical Products Co., Ltd., Medical Protective Mask - Folding Type. The packaging for these respirators indicates they meet GB19083-2010 (the Chinese standard for Technical Requirements for Protective Face Mask for Medical Use).

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 99.22% and 93.76%, respectively. Eight respirators measured more than 95%. Two 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.

This product has head bands/straps. 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 respirators 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 30, 2020

**Report Prepared:** June 30, 2020

**Manufacturer:** Shandong Haidike Medical Products Co., Ltd.

**Item Tested:** Medical Protective Mask - Folding Type

**Country of Certification:** China (GB19083-2010)

<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>12.1</td>
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<td>96.27</td>
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<tr>
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<td>10.4</td>
<td>6.24</td>
<td>6.24</td>
<td>93.76</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 93.76  Maximum Filter Efficiency: 99.22

- 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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![Medical Protective Mask](image)

**Certificate of Conformity**

Product name: Medical Protective Mask

Specifications:
- Folding Type 11.5cm x 15cm
- Raw Materials: 60% Non-woven fabric, 40% Melt-blown fabric
- GB19083-2010

Additional Information:
- Storage: Keep away from direct sunlight, do not store in high temperatures, humidity, or corrosive gases. Store in a clean, dry, well-ventilated environment.
- Package: 20 pieces per box
- Production date and expiration date: Must be checked and marked on the package
- Manufacturer: Shandong Haidike Medical Products Co., Ltd.
- Address: Tianfu Road, Dongcheng District, Shan County, Heze City, Shandong Province, China

Made in China
Manufacturer: Shandong Haicike Medical Products Co., Ltd.
Add: Tianfu Road, Dongcheng District, Shan County, Heze City, Shandong Province, China.
Tel: +86-530-4660062
Medical Protective Mask

Folding Type 11.5cm×15cm  1Pcs

Performance:
The appearance of the product should be clean, no obvious dirt, no odor and color difference, and soft. The surface should not be damaged, cracked, and it should be intact and straight, etc. No deformation or other obvious defects are allowed.

Contraindications: It is forbidden for those who are allergic to materials.

Warnings:
1. One-time use, destroy after using.
2. The packaging is damaged or leaking, and it is forbidden to use.

Storage and transportation conditions: This product should be stored in a cool, dry, clean, dark place, no corrosive gas, and well-ventilated room after using. The means of transportation should be clean and hygienic, and isolation from the fire source.

Manufacturer: Shandong Haidike Medical Products Co., Ltd.

LOT: 200520 2030 05 20 2021 04 20

Head loop
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