NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shenzhen FITTOP Health Technology Co., Ltd.
Model Tested: FM80
Date Tested: May 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 provided with the samples received; however, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 98.76% and 20.40%, respectively. Three respirators measured more than 95%. Seven 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).
NPPTL COVID-19 Response: International Respirator Assessment

**Evaluation of International Respirators**

**Test:** Modified TEB-APR-STP-0059

**Date Tested:** May 22, 2020

**Report Prepared:** May 26, 2020

**Manufacturer:** Shenzhen FITTOP Health Technology Co., Ltd.

**Item Tested:** FM80

**Country of Certification:** China (GB2626-2006, 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>6.6</td>
<td>72.0</td>
<td>72.0</td>
<td>28.00</td>
</tr>
<tr>
<td>2</td>
<td>85</td>
<td>11.5</td>
<td>1.45</td>
<td>1.58</td>
<td>98.42</td>
</tr>
<tr>
<td>3</td>
<td>85</td>
<td>7.7</td>
<td>76.1</td>
<td>78.1</td>
<td>21.90</td>
</tr>
<tr>
<td>4</td>
<td>85</td>
<td>12.6</td>
<td>1.24</td>
<td>1.24</td>
<td>98.76</td>
</tr>
<tr>
<td>5</td>
<td>85</td>
<td>6.9</td>
<td>69.1</td>
<td>69.5</td>
<td>30.50</td>
</tr>
<tr>
<td>6</td>
<td>85</td>
<td>7.2</td>
<td>77.6</td>
<td>77.6</td>
<td>22.40</td>
</tr>
<tr>
<td>7</td>
<td>85</td>
<td>7.7</td>
<td>71.5</td>
<td>71.5</td>
<td>28.50</td>
</tr>
<tr>
<td>8</td>
<td>85</td>
<td>8.0</td>
<td>1.37</td>
<td>1.77</td>
<td>98.23</td>
</tr>
<tr>
<td>9</td>
<td>85</td>
<td>7.4</td>
<td>79.6</td>
<td>79.6</td>
<td>20.40</td>
</tr>
<tr>
<td>10</td>
<td>85</td>
<td>7.4</td>
<td>77.5</td>
<td>77.5</td>
<td>22.50</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 20.40  Maximum Filter Efficiency: 98.76

- 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.
P-Mask KN95 Mask
Filtering Particulate Protection Respirator

Product Description

[Product Model] FM80


[Product Description] The mask's 3D shape is designed according to the ergonomics of the human face to ensure the tightness and increase the breathing capacity of the mask, which greatly improve the air permeability and make it more comfortable to wear and breathe.

[Range of Application] Suitable for protection of PM2.5 haze particles, food, chemicals, coal dust, cement dust, metal smelting and processing manufacturing.

[How to Wear] Open the mask fully, position the mask with metal nose strip up. After wearing, use both hands to press the metal nose strip to fit the bridge of your nose and achieve a better protection effect.

[Note] Before using, check whether the packaging is intact, and confirm the marked expiration date of the outer package and use within the expiration date.

[Storage Conditions] It should be stored in a dry, well-ventilated, non-corrosive gas environment, away from fire sources and flammable materials.

[Transportation Conditions] Avoid heavy pressure, direct sunlight and humidity during transportation.

[Production Date] As indicated on the package

[Validity] Within three years

SHENZHEN FITTOP HEALTH TECHNOLOGY CO., LTD.
Add: 5E, BLDG4, Hualian Industrial Estate, Huaining Road, Baoan, Longhua District, Shenzhen, China.
Email: info@fittop.com
Web: www.fittop.net
NPPTL COVID-19 Response: International Respirator Assessment
NPPTL COVID-19 Response: International Respirator Assessment
NPPTL COVID-19 Response: International Respirator Assessment