NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Zhejiang Shaohua Medical Equipment Co., Ltd.
Model Tested: 3D protective mask
Date Tested: June 1, 2021


Thirty respirators were submitted for evaluation. The samples were tested using the 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 99.81% and 97.09%, respectively. All thirty respirators measured more than 95% filter efficiency.

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 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).
NPPTL COVID-19 Response: International Respirator Assessment

Evaluation of International Respirators

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

**Date Tested:** June 1, 2021

**Report Prepared:** June 1, 2021

**Manufacturer:** Zhejiang Shaohua Medical Equipment Co., Ltd.

**Item Tested:** 3D Protective Mask

**Country of Certification:** China (GB2626-2006), European (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>16.2</td>
<td>0.50</td>
<td>0.50</td>
<td>99.50</td>
</tr>
<tr>
<td>2</td>
<td>85</td>
<td>17.0</td>
<td>0.29</td>
<td>0.29</td>
<td>99.71</td>
</tr>
<tr>
<td>3</td>
<td>85</td>
<td>13.0</td>
<td>1.62</td>
<td>1.62</td>
<td>98.38</td>
</tr>
<tr>
<td>4</td>
<td>85</td>
<td>16.7</td>
<td>0.34</td>
<td>0.34</td>
<td>99.66</td>
</tr>
<tr>
<td>5</td>
<td>85</td>
<td>15.6</td>
<td>0.29</td>
<td>0.29</td>
<td>99.71</td>
</tr>
<tr>
<td>6</td>
<td>85</td>
<td>20.6</td>
<td>1.75</td>
<td>1.75</td>
<td>98.25</td>
</tr>
<tr>
<td>7</td>
<td>85</td>
<td>18.6</td>
<td>0.55</td>
<td>0.55</td>
<td>99.45</td>
</tr>
<tr>
<td>8</td>
<td>85</td>
<td>18.3</td>
<td>0.23</td>
<td>0.23</td>
<td>99.77</td>
</tr>
<tr>
<td>9</td>
<td>85</td>
<td>12.7</td>
<td>1.27</td>
<td>1.27</td>
<td>98.73</td>
</tr>
<tr>
<td>10</td>
<td>85</td>
<td>13.2</td>
<td>0.93</td>
<td>0.93</td>
<td>99.07</td>
</tr>
</tbody>
</table>

**Minimum Filter Efficiency:** 98.25%  **Maximum Filter Efficiency:** 99.77%

- 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.
NPPTL COVID-19 Response: International Respirator Assessment

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059
Date Tested: June 1, 2021
Report Prepared: June 1, 2021
Manufacturer: Zhejiang Shaohua Medical Equipment Co., Ltd.
Item Tested: 3D Protective 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>11</td>
<td>85</td>
<td>20.4</td>
<td>0.22</td>
<td>0.22</td>
<td>99.78</td>
</tr>
<tr>
<td>12</td>
<td>85</td>
<td>17.1</td>
<td>0.40</td>
<td>0.40</td>
<td>99.60</td>
</tr>
<tr>
<td>13</td>
<td>85</td>
<td>17.6</td>
<td>0.27</td>
<td>0.27</td>
<td>99.73</td>
</tr>
<tr>
<td>14</td>
<td>85</td>
<td>18.0</td>
<td>0.40</td>
<td>0.40</td>
<td>99.60</td>
</tr>
<tr>
<td>15</td>
<td>85</td>
<td>18.5</td>
<td>0.34</td>
<td>0.34</td>
<td>99.66</td>
</tr>
<tr>
<td>16</td>
<td>85</td>
<td>21.4</td>
<td>0.45</td>
<td>0.45</td>
<td>99.55</td>
</tr>
<tr>
<td>17</td>
<td>85</td>
<td>19.0</td>
<td>0.25</td>
<td>0.25</td>
<td>99.75</td>
</tr>
<tr>
<td>18</td>
<td>85</td>
<td>19.8</td>
<td>0.21</td>
<td>0.21</td>
<td>99.79</td>
</tr>
<tr>
<td>19</td>
<td>85</td>
<td>15.1</td>
<td>1.45</td>
<td>1.45</td>
<td>98.55</td>
</tr>
<tr>
<td>20</td>
<td>85</td>
<td>16.0</td>
<td>1.67</td>
<td>1.67</td>
<td>98.33</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 98.33%  Maximum Filter Efficiency: 99.79%

- 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.
NPPTL COVID-19 Response: International Respirator Assessment

Evaluation of International Respirators

**Test:** Modified TEB-APR-SP-0059  
**Date Tested:** June 1, 2021  
**Report Prepared:** June 1, 2021  
**Manufacturer:** Zhejiang Shaohua Medical Equipment Co., Ltd.  
**Item Tested:** 3D Protective Mask  
**Country of Certification:** China (GB2626-2006), European (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>21</td>
<td>85</td>
<td>14.4</td>
<td>1.29</td>
<td>1.29</td>
<td>98.71</td>
</tr>
<tr>
<td>22</td>
<td>85</td>
<td>20.0</td>
<td>0.19</td>
<td>0.19</td>
<td>99.81</td>
</tr>
<tr>
<td>23</td>
<td>85</td>
<td>17.5</td>
<td>0.37</td>
<td>0.37</td>
<td>99.63</td>
</tr>
<tr>
<td>24</td>
<td>85</td>
<td>16.7</td>
<td>0.41</td>
<td>0.41</td>
<td>99.59</td>
</tr>
<tr>
<td>25</td>
<td>85</td>
<td>18.2</td>
<td>2.68</td>
<td>2.91</td>
<td>97.09</td>
</tr>
<tr>
<td>26</td>
<td>85</td>
<td>18.7</td>
<td>0.26</td>
<td>0.26</td>
<td>99.74</td>
</tr>
<tr>
<td>27</td>
<td>85</td>
<td>16.8</td>
<td>1.46</td>
<td>1.47</td>
<td>98.53</td>
</tr>
<tr>
<td>28</td>
<td>85</td>
<td>21.8</td>
<td>0.22</td>
<td>0.22</td>
<td>99.78</td>
</tr>
<tr>
<td>29</td>
<td>85</td>
<td>15.7</td>
<td>1.17</td>
<td>1.17</td>
<td>98.83</td>
</tr>
<tr>
<td>30</td>
<td>85</td>
<td>16.0</td>
<td>0.57</td>
<td>0.57</td>
<td>99.43</td>
</tr>
</tbody>
</table>

**Minimum Filter Efficiency:** 97.09%  
**Maximum Filter Efficiency:** 99.81%

- 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.
NPPTL COVID-19 Response: International Respirator Assessment

ER-PRO™ Protective Respirator Mask

Protect Against:
- Droplets
- Dust & Fog
- Liquid Splash
- PM2.5 Particles

50 PACKS

Individually Sealed

3-Dimensional Fit • 4-Layer with Nano-Fiber Filter • Adjustable Noseband • Leak-Free
NPPTL COVID-19 Response: International Respirator Assessment

INSTRUCTIONS

- Hold the respirator in hand with adjustable noseband on top, allowing the ear loops hang freely.
- Press the respirator firmly against your face with the noseband on the bridge of your nose.
- Stretch and position ear loops behind each side of ears.
- Use both hands, mold noseband to the shape of your nose.
- To test fit: cup both hands over the respirator without disturbing position, and then inhale vigorously. If air leaks around the edges, reposition or adjust the ear loop for better fit.
- Follow fitting instruction during each use to achieve proper fit.

WARNING

- Must read fitting instruction and use limitation before use.
- Wearers should be trained in the proper use, including fit testing, in accordance with applicable safety and health standards for the contaminant and exposure level in the work area as per OSHA guideline, 29 CFR 1910.134.
- If you CANNOT achieve a proper seal, DO NOT enter the contaminated area.
- For additional information on this product, please call 1-800-338-0212.

CAUTIONS & LIMITATION

- Do not use if oxygen concentration is below 19.5%.
- Do not use in toxic atmospheres immediately dangerous to life or health.
- Failure to properly use and maintain this product could result in injury or death.
- Do not use if satisfying fit is not achieved.
- This product is disposable. Do not re-use after cleaning.
- This respirator has not been evaluated for surgical use.

This disposable protective mask is manufactured according to GB 2626-2006 and EN149:2001+A1:2009 and is intended for use for non-medical purposes.
NPPTL COVID-19 Response: International Respirator Assessment
NPPTL COVID-19 Response: International Respirator Assessment

Wearing instructions:

- Make sure the metal nose clip is facing up.
- Put on a mask and clasp the ear straps behind your ears.
- Adjust the mask to fit the face completely.
- Press the nose clip against the bridge of the nose.
- Cover the mask with your hands and exhale then inhale. Adjust the mask until no gas leaks out.

⚠️ WARNING

This respirator helps protect against certain particles. Misuse can result in sickness or death.

[Product name] 3D protective mask
[Product material] KN95 filter
[Wearing method] ear-hook
[Executive Standard] GB2626–2006 KN95
NPPTL COVID-19 Response: International Respirator Assessment
NPPTL COVID-19 Response: International Respirator Assessment