NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Raxwell Industrial Technology (Shanghai) Co., Ltd.
Model Tested: RX9501
Date Tested: May 13, 2020

These findings pertain to the Raxwell Industrial Technology (Shanghai) Co., Ltd., model RX9501. 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 was 99.69% and 99.48%, 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)](#).
Test: Modified TEB-APR-STP-0059

Date Tested: May 13, 2020

Report Prepared: May 13, 2020

Manufacturer: Raxwell Industrial Technology (Shanghai) Co., Ltd.

Item Tested: RX9501

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>8.6</td>
<td>0.27</td>
<td>0.31</td>
<td>99.69</td>
</tr>
<tr>
<td>2</td>
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<td>0.38</td>
<td>0.47</td>
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<tr>
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<tr>
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<td>8.4</td>
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</tr>
<tr>
<td>10</td>
<td>85</td>
<td>8.4</td>
<td>0.32</td>
<td>0.39</td>
<td>99.61</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 99.48    Maximum Filter Efficiency: 99.69

- 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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存储条件

本产品需储存于通风良好，避光，干燥的环境中，远离火源，污染物
储存湿度： -20°C 至 30°C 之间，相对湿度 < 80％
储存期限： 5年

使用说明

1. 不使用说明使用口罩或在污染环境中佩戴不当，会严重影响口罩的
   佩戴效果并可能导致疾病，受污染或死亡
2. 使用前，佩戴者必须首先经过口罩正确佩戴的培训，并遵循相关的
   安全及健康标准
3. 建议佩戴者在使用前进行密合性测试，可以参考国内相关法规或标准
4. 如果出现以下情况，请更换或重新佩戴
   - 口罩出现破洞
5. 如果出现头晕、困倦等症状，请离开污染区域
6. 本口罩是为职业/专业的成年人设计，本口罩不适用于儿童

佩戴方式

1. 鼻夹向外，双手分别握住一边耳带，确保鼻夹向上
2. 戴上口罩，下巴置于口罩内，双手将耳带拉于耳后
3. 调整到舒适位置，使口罩贴合面部
4. 将双手的食指及中指按压调节鼻夹，直至紧贴鼻梁

用途

用于防止吸入生产加工过程中所产生的微粒及患者作业中所产生的
液体

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IMPORTANT

Before use, the wearer must read and understand these user
Instructions. Keep these instructions for reference. See information supplied by the manufacturer.

USES

Mechanically generated dusts, mists from processing minerals
including coal, iron ore, silica, cotton, flour and certain other
substances in concentrations up to ten times the Occupational
Exposure Standard or according to local.
DO NOT USE FOR paint spraying and sandblasting applications or
for protection against gases and vapors. Not for use in oil mist
atmospheres.

STORAGE CONDITIONS AND SHELF LIFE

Shelf life of unopened product is 5 years from date of manufacture
when stored within temperature range of -20°C to 38°C and at
less than 80% relative humidity.

FITTING INSTRUCTIONS

1. With nosepiece facing away from you, hold the earloop strap in
each hand with the nosepiece up.
2. Position the respirator under the chin.
3. Pull each strap over the ear. Adjust as comfortable as possible.
4. Mold the nosepiece to the shape of the nose bridge by pushing
inwards while moving your finger tips down both sides.

Step 1 Step 2 Step 3 Step 4
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