NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Baoji Taidakang Medical Technology Co., Ltd
Model Tested: Folding Mask with Ear Loop
Date Tested: May 13, 2020

These findings pertain to the Baoji Taidakang Medical Technology Co., Ltd., Folding Mask with Ear Loop. The labeling for these respirators indicate 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 99.51% and 99.25%, 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).
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Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: May 13, 2020

Report Prepared: May 13, 2020

Manufacturer: Baoji Taidakang Medical Technology Co., Ltd

Item Tested: Folding Mask with Ear Loop

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>12.8</td>
<td>0.51</td>
<td>0.51</td>
<td>99.49</td>
</tr>
<tr>
<td>2</td>
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<td>13.8</td>
<td>0.49</td>
<td>0.49</td>
<td>99.51</td>
</tr>
<tr>
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<td>0.64</td>
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<tr>
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<tr>
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<tr>
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<td>14.2</td>
<td>0.60</td>
<td>0.60</td>
<td>99.40</td>
</tr>
<tr>
<td>10</td>
<td>85</td>
<td>13.9</td>
<td>0.75</td>
<td>0.75</td>
<td>99.25</td>
</tr>
</tbody>
</table>


- 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.
医用防护口罩
Protective Face Mask For Medical Use

使用方法
1. 将口罩展开，将口鼻罩在面罩上；
2. 双手分别拉住两耳带，将口罩戴在脸上；
3. 将口罩拉平在脸上，调节带紧至贴紧脸部

注意事项：
1. 本产品为一次性用品，禁止重复使用。
2. 使用后请丢弃，使用前检查包装是否完好，对包装破损、生产日期、有效期进行确认，并在有效期内使用。
3. 本产品为一次性用品，禁止重复使用。
4. 本产品不适用于非医用环境。
5. 使用前请检查包装是否完好，使用前请查看包装破损。
6. 不适用于面部过敏者使用。
7. 本产品适用于医护人员在有创操作过程中佩戴。

生产日期/生产批号：见包装
灭菌有效期：三年

存放条件：常温、干燥、避光

执行标准：GB 19083-2010
生产许可证编号：津药监械生产许20200014号
注册证编号：津械注准20202140026

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