NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangdong Energy Fortress Pharmaceutical Co., Ltd.
Model Tested: KN95 Protective Respirator
Date Tested: April 29, 2020

These findings pertain to the Guangdong Energy Fortress Pharmaceutical Co., Ltd., KN95 Protective Respirator. The product information provided with 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-STP-0059. This modified assessment plan can be found here.

A certificate of approval was not provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 100.00% and 95.36%, 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).
Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059
Date Tested: April 29, 2020
Report Prepared: May 1, 2020
Manufacturer: Guangdong Energy Fortress Pharmaceutical Co., Ltd.
Item Tested: KN95 Protective Respirator
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>
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<td>37.8</td>
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<td>23.8</td>
<td>0.00</td>
<td>0.00</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 95.36  Maximum Filter Efficiency: 100.00

- 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.
1. 面向口罩无金属鼻夹的一面，双手各拉住一边耳带，使鼻夹位于口罩上方。
2. 将口罩戴在面部，将两边耳带拉至耳后，调整耳带至感觉尽可能舒适。
3. 调整口罩位置，下边缘包住下颌，使其适合脸部并全部遮住口和鼻。
4. 用双手手指按压调整金属鼻夹两侧，直到完全压成鼻梁形状，确保密合性。

产品名称：KN95防护口罩（自吸过滤式防颗粒呼吸器）
主要原材料：内层：无纺布；外层：无纺布；过滤层：熔喷布滤材层。
执行标准：GB 2626-2006
过滤元件级别：GB 2626-2006 KN95
应用范围：防护PM2.5雾霾、飞沫等有害颗粒物；也适用于食品加工、机械制造、五金化工业、卫生清洁、加工打磨等需要粉尘防护的相关行业。
建议储存条件：-10℃～40℃，相对湿度≤85%，避免阳光直射。
委托商：广东微量元素生物科技有限公司
地址：广东省广州市黄埔经济开发区永和经济区新业路58号
联系电话：400-058-1008
生产商：广东能量堡垒制药有限公司
地址：广东省广州市白云区良沙路3169号102
生产日期：见封口
保存期：2年
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