NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd.
Model Tested: KN95 Particulate Protective Mask
Date Tested: June 11, 2020

These findings pertain to the Guangdong Nuokang Medical Technology Co., Ltd., KN95 Particulate Protective Mask. The packaging for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Nine 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 98.22% and 91.33%, respectively. Two 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).
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Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059
Date Tested: June 11, 2020
Report Prepared: June 11, 2020
Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd.
Item Tested: KN95 Particulate Protective Mask
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>
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<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>6.3</td>
<td>4.31</td>
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<td>5.5</td>
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<td>92.93</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 91.33  Maximum Filter Efficiency: 98.22

- 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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诺康医疗

KN95 颗粒物防护口罩

注意事项
1. 本产品请保存在清洁、卫生、通风、干燥的地方，不可水洗，不可自行改造；
2. 请勿与他人交互使用；
3. 请妥善保管，儿童请在大人的监督指导下使用；
4. 包装破损请勿使用，不卫生、不适合继续使用时请更换新口罩。

产品名称：KN95 颗粒物防护口罩
材质：熔喷无纺布、耳带、弹力头带
执行标准：GB2626-2006
规格：18cm×13cm
数量：1只/袋
有效期：包装未拆封三年
生产日期：见包装

2020-03-11
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