NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Xiamen Luan'an Protective Equipment Co., Ltd.
Model Tested: Eversafe KN95 Self-Priming Filter Respirator
Date Tested: May 5, 2020

These findings pertain to the Xiamen Luan'an Protective Equipment Co., Ltd., Eversafe KN95 Self-Priming Filter Respirator. The information included with 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-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 98.16% and 97.56%, respectively. All nine 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:** May 5, 2020  
**Report Prepared:** May 6, 2020  
**Manufacturer:** Xiamen Luan’an Protective Equipment Co., Ltd.  
**Item Tested:** Eversafe KN95 Self-Priming Filter 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>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>12.6</td>
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<td>1.96</td>
<td>98.04</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 97.56  
Maximum Filter Efficiency: 98.16

- 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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立体设计
产品等级：KN95

使用范围
该产品适用于过滤空气中的颗粒物，烹饪、烟、雾、微生物，如烟草、血液、液体、分泌物，适用于工业用场所以及各类环境。

产品主要性能
过滤效率：盐性过滤效率≥95%。
呼吸阻力：总呼吸阻力≤350pa，呼气阻力≤250pa。
头带：头带承受的拉力应在100N±10%。

【产品主要结构】
本产品由聚乙烯布、过滤材料、鼻夹、口鼻夹紧装置、熔接、包装而成。

使用方法
1. 按照说明书选择合适型号，拉伸口罩带，鼻夹金属软条向上。
2. 将手部食指及中指由中央顶部向两侧同时扩张鼻夹，直至紧贴鼻梁。
3. 双手轻轻捏住口罩带并进行正压及负压测试，确保口罩的适用性。

适应性检查
正压检查：以双手轻捏口罩，然后进行呼吸，空气应不会从口罩边缘泄漏。
负压检查：以双手轻轻捏口罩，然后进行呼吸，口罩边缘不会凹陷。
如有空气从口罩边缘进入，则佩戴不当，须再次调整头带及鼻夹。

产品名称：一次性医用防护口罩
产品型号：29501
执行标准：GB2626-2006
生产许可证号：（京）XK06-001-00056
生产日期：见包装标示处
有效期：5年
包装数量：50只/盒
贮存方法：请储存在干燥通风的环境，储存温度为-20°C～-40°C，相对湿度不大于85%。

制 造 商：厦门安斯沃医用有限公司
注册地址：厦门市同安区利路三号79-85号（3#厂房）二楼、三楼、四楼
生产地址：厦门市同安区利路三号79-85号（3#厂房）二楼、三楼、四楼
联系电话：0592-7209618
网 址：http://www.xawm.com
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