NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Huizhou Zhongna Medical Technology Co., Ltd
Model Tested: Anysound KN95 Self-Priming Filter & Anti-Particle Respirator
Date Tested: April 22, 2020


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 83.41% and 77.30%, respectively. All ten 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: April 22, 2020

Report Prepared: April 23, 2020

Manufacturer: Huizhou Zhongna Medical Technology Co., Ltd

Item Tested: Anysound KN95 Self-Priming Filter & Anti-Particle Respirator


<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>10.0</td>
<td>16.70</td>
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<td>83.30</td>
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</table>

Minimum Filter Efficiency: 77.30  Maximum Filter Efficiency: 83.41

- 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.
KN95
SELF-PRIMINGFILTER & ANTI-PARTICLE RESPIRATOR

Enhanced respirator
Low Respiratory Resistance
A comfortable

FPP2  FDA  CE  EN 149:2001+A1:2009  20 PCS/BOX

[Notice]

- It should be removed immediately when the wearer is clearly having difficulty breathing. It is not recommended to wear this product in poor air quality environment (pollutants and anoxic etc.).
- It cannot be used when the ambient humidity is more than 60 degrees or the ambient oxygen content is less than 19.5%.
- It cannot be used in toxic gas environment (cannot replace gas mask) it is only applicable to the protection of non-oily particles.
- The hair under the tight frame can cause the mask to leak.
- It is not recommended for children, pregnant women, or the elderly to wear this product, due to the existence of certain breathing resistance.
- The mask filter is made of particulate N95 material and filters the invisible dust.
- The mask can filter 95% over non-oil particles.
- Application: Rubber, crystal, fur, synthetic metal forging, batteries, synthetic chemicals, building materials, nuclear industry, mining oil, shipbuilding and metallurgy, sanitation, coal paint industry, automobile manufacturing industry, etc.

Inspection method:
Pay attention to check whether the mask package is broken, components are normal. If there is any stain or damage, please do not use. Before entering into the work area, the mask must be checked for tightness to the face. Please re-wear when feeling leakage. You can wear this mask to the work area to work if there is no sense of leakage.

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Tel: 0752-2397229  0752-2397219

Made in China
Method of Wearing

1. Spread the mask with both hands, face the inner side of the mask, and place the nose clip over the mask.
2. Press the index finger of both hands from the middle to both sides, and make the bridge stick to the bridge according to the switch plasticity of the bridge.
3. Pull the elastic band to the back of the ear, adjust the mask and elastic band to feel comfortable.
4. Cover the mask by hand and exhale. If any gas leaks from the edge of the mask, adjust the mask again until no gas leaks.

Model: KN95
Product: Protective Mask (Non-sterile)
Material: Non-woven, melt blown filter material
Date of Manufacture: See outer package
Shelf Life: 2 years

Filtration efficiency BFE95%
We are the waves of the same sea
the peoples of the same earth

[Usage method]
1. Place the nose clip over the nose and the mask over your face.
2. After pulling the ear loop to the back, adjust the mask as comfortably as possible.
3. From the middle of the nose to the bridge of the nose, pull the nose clip until it is flush with the nose.
4. Check that the mask is sealed and comfortable.

[Precautions]
1. When the oxygen concentration is lower than 19.5% in anoxic environment, this mask is not suitable for use.
2. The concentration of pollutants is too high to endanger life or health.
3. This mask is not suitable to use this mask when the degree is high.
4. This mask shall not be used to protect harmful gas or steam.
5. When it is found that the mask is contaminated, damaged or the respiratory resistance changes, the mask should be replaced in case of major conditions.

[Storage]
Store at room temperature and dry place. Validity period: 3 years.
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