NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd
Model Tested: KN95 Protective Face Mask
Date Tested: November 5, 2020

These findings pertain to the Guangdong Nuokang Medical Technology Co., Ltd., model KN95 Protective Face 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).

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 61.60% and 34.30%, 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 respirators 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: November 5, 2020

Report Prepared: November 5, 2020

Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd

Item Tested: KN95 Protective Face 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>9.6</td>
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<td>35.90</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 34.30%    Maximum Filter Efficiency: 61.60%

- 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
5-LAYER NON-WOVEN PROTECTIVE FACE MASK

Structure
This product is made of non-woven fabric, melt-blown filter, nose clip and mask band.

Scope of application
Helps filter out dust, bacteria, smoke & pollen

Instructions and precautions
1. Check the package is on good condition or not before using. And confirm the external packing mark, production date and validity period, and use them within the validity period.

2. For people who are not allergic to non-woven fabric.

3. The product has been used, it shall be handled according to the requirements of the environmental protection department.

Storage
Store in a dry and ventilated, no corrosive gases place, keep away from fire sources and inflammables. Products should be sealed package and protected from moisture during transportation.

Product name: KN95 Protective Face Mask
Color: white
Material: Melt-blown filter, Non-woven Fabric
Production Date: (dd/mm/yy)
Validity: 2 years
GB2626-2006 Standard (China)
KN95
5-LAYER NON-WOVEN
PROTECTIVE FACE MASK

METHOD OF USE

01 The nose clip part is facing up, the side without nose clip is facing the face, and the ear straps are pulled on each hand;

02 Face the mask against the chin first, and pull the ear-band back to the ear and hang it on the ear until it feels comfortable;

03 Place the fingers of both hands in the middle of the nose clip and press inwardly according to the shape of the nose bridge to conform to the shape of the nose bridge;

04 Face the mask against the chin first, and pull the ear-band back to the ear and hang it on the ear until it feels comfortable;

05 Put your hands on your face when using, and check the tightness with your face.

Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd
ADDRESS: NO18, Housha Road, Dongguan City, Guangdong Province, China
Contact: +86-769-81266677
INCLUSION CERTIFICATE

product name: five layers KN95 protective face mask

PRODUCT: FIVE LAYERS KN95 PROTECTIVE FACE MASK

size: 105*160mm

EXECUTIVE STANDARD: GB2626-2006

main raw materials:

outer layer: white PP non-woven fabric (double layers)

inner layer: high efficiency filter melt-blown fabric

inner layer: white PP non-woven fabric (double layers)

production batch: KJ20200420

LOT NO.: KJ20200420

production date: 2020/4/18

expiration date: 2022/4/17

manufacturer: guangdong nuokang medical technology co., ltd.

address: room 207, building 14, no. 10, houjie huanhu road, houjie town, dongguan, guangdong province.

use notes:

1. this product is only suitable for filtering particles in the air polluted environment of daily life.

2. please check if the mask package is intact.

3. recommend replacing the mask regularly, don't use if for long term.

4. if there is discomfort or adverse reaction, it is recommended to stop using.

5. the product shall be stored in dry, ventilated and non corrosive gas environment.

recommended wearing time is for 4 hours.
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