

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Dongguan Oukangda Medical Technology Co., Ltd.

Model Tested: Self-Priming Filter Respirator

Date Tested: April 29, 2020

These findings pertain to the Dongguan Oukangda Medical Technology Co., Ltd., Self-Priming Filter Respirator. 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 observed was 93.76% and 20.00%, 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 \(during known shortages\)](#).

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: April 29, 2020

Report Prepared: May 4, 2020

Manufacturer: Dongguan Oukangda Medical Technology Co., Ltd.

Item Tested: Self-Priming Filter Respirator

Country of Certification: China (GB2626-2006)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	11.5	6.24	6.24	93.76
2	85	6.4	7.09	7.27	92.73
3	85	6.7	8.62	8.62	91.38
4	85	6.4	7.99	8.11	91.89
5	85	5.3	72.30	72.30	27.70
6	85	4.5	74.20	75.13	24.87
7	85	4.2	78.20	80.00	20.00
8	85	3.5	75.00	77.80	22.20
9	85	4.3	75.27	76.01	23.99
10	85	4.5	75.94	77.48	22.52
Minimum Filter Efficiency: 20.00			Maximum Filter Efficiency: 93.76		

- 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.

78.4

PROTECTIVE MASK

GB2626-2006 (Civil Grade)

KN95



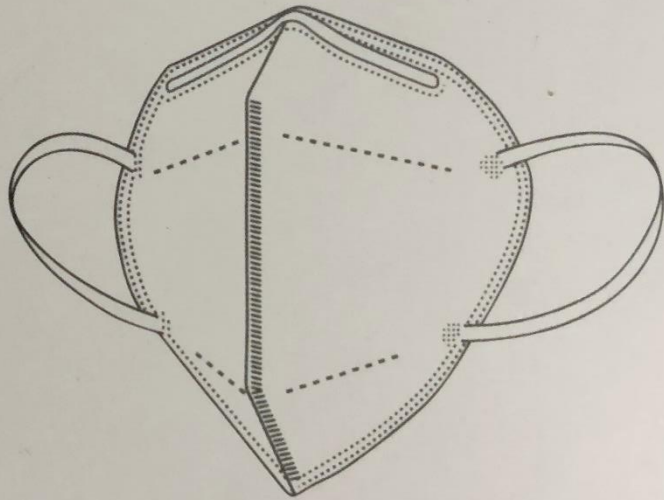
Odorless



Nonirritating



Nonallergic




10

PCS

Standard size/Earloop

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How to Use



1. Open the mask to make the nose clip at the top, and pull the ear straps with both your hands.
2. Hold the mask against your chin to completely cover your nose and mouth.
3. Pull the ear straps behind your ears and adjust them to make you feel comfortable.
4. Use both your hands to adjust the shape of the nose clip. Place your fingers in the middle of the nose clip and press it inwards while moving your fingertips along both sides of the nose clip until it is pressed to fit the bridge of your nose. (Making the nose clip get a seal with only one hand may affect the tightness of the mask).
5. Cover the mask with your hand and exhale vigorously. If you feel the air escaping from the nose clip, it is required to tighten the nose clip; if the air escapes from the edge of the mask, readjust the headband to ensure tightness.

Inspection Method

Before use, check whether the package of the mask is damaged and the components are intact. In case of any stain or damage, discontinue use immediately. Before entering the work area, it is required to check the air tightness of the mask. If you feel a leak, please wear it again according to the instructions for how to wear a mask. You can enter the work area only after feeling no leak. (If you feel the respiratory resistance is obviously increased or the mask falls short of the standard for use, it is recommended to replace the mask immediately.)

KN95

GB2626- 2006
(Civil Grade)

This dust mask is used to prevent non-oily suspended particles.
Filtration Efficiency $\geq 95\%$.

Do not use if package is damaged!
Please refer to the manual before use and use a mask correctly!

Product Parameters


Product Name: KN95 Protective Masks
Main Material: Nonwoven Fabric, Meltblown Fabric
Protection Level: KN95
Expiration Date: 2 Years
See the packaging indication for production batch number and expiration date.

Precautions

1. If the package is damaged, it is forbidden to use the mask. It is limited to respiratory protection against non-oily particles only.
2. It is recommended to store in a dry, ventilated, non-corrosive gas environment below a humidity of 80%. Keep away from ignition sources and flammable materials.
3. This Product Is Not Applicable To Special Industries Such As Anoxic Environment, Underwater Operation, Fire Control And Industrial Dust Protection Or To Respiratory Protection Of Infants.
4. Do Not Wear A Mask If Unventilated, Hard In Breathing Or During Sleep.
5. People With Abnormal Heart And Lung Functions Should Use Masks With Caution.
6. If A Mask Is Damaged Or You Feel The Respiratory Resistance Is Obviously Increased, Replace It In Time.
7. In Case Of Any Discomfort Or Adverse Reactions During Use, Discontinue Use immediately.
8. Do Not Reuse.

Nonapplicable Scenes

- Nonapplicable Scenes
- Do not use in an environment above 50°C.
- Do not use in an environment with an oxygen content of less than 20% ,
- Do not use in a toxic gas environment.
- Not recommended for children, pregnant women or the elderly,



MADE IN CHINA

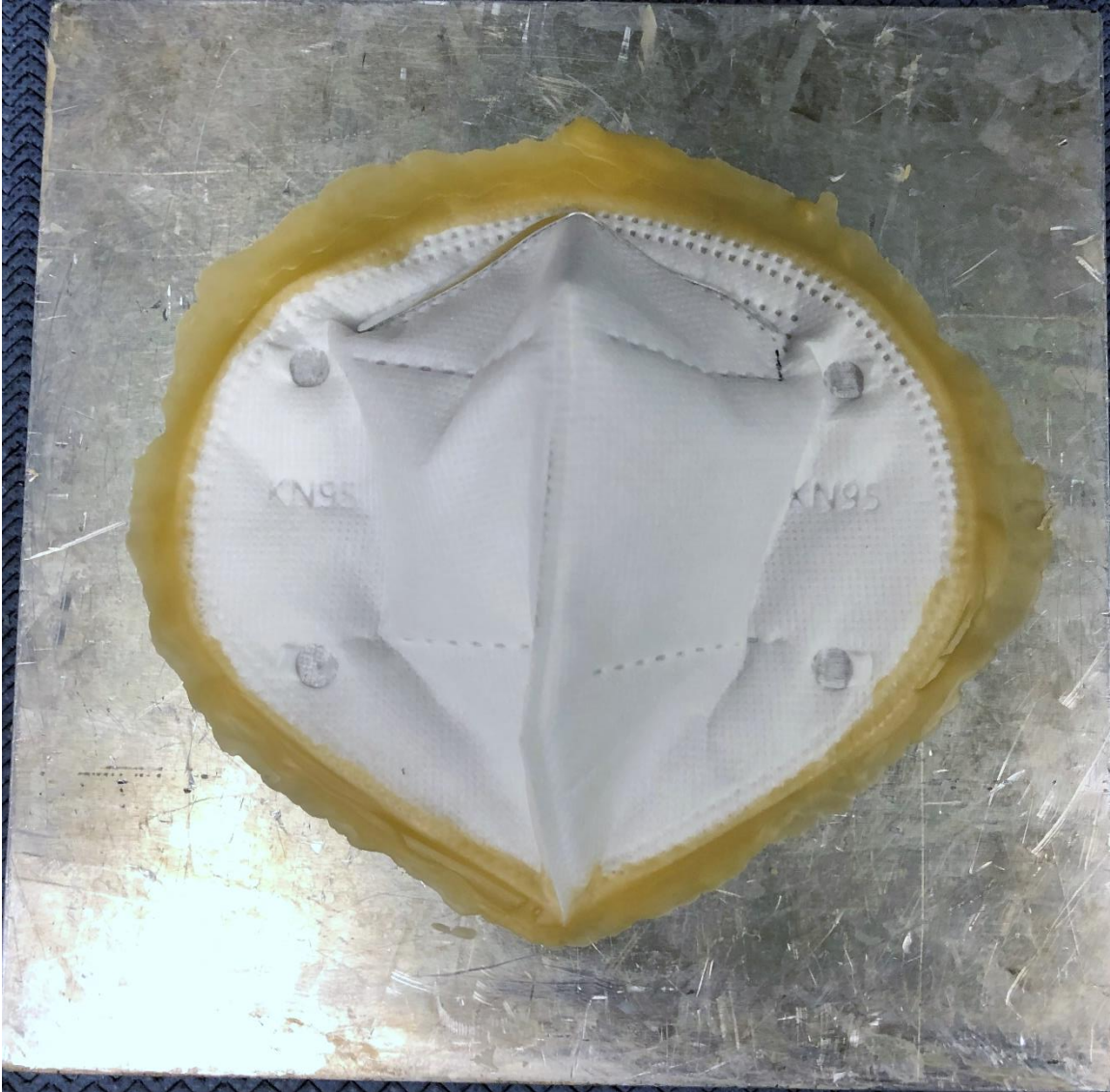
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