

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangdong Mingxiang Medical Instrument Co., Ltd.

Model Tested: N95 Face Mask

Date Tested: June 11, 2020

These findings pertain to the Guangdong Mingxiang Medical Instrument Co., Ltd., N95 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) and EN149:2001+A1:2009 (the European standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking).

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 85.10% and 56.90%, 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: June 11, 2020

Report Prepared: June 11, 2020

Manufacturer: Guangdong Mingxiang Medical Instrument Co., Ltd.

Item Tested: N95 Face Mask

Country of Certification: China (GB2626-2006, EN149:2001+A1:2009)

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	4.7	33.4	35.3	64.70
2	85	7.1	15.9	15.9	84.10
3	85	7.2	17.0	17.0	83.00
4	85	4.9	37.9	40.6	59.40
5	85	6.1	22.0	22.0	78.00
6	85	4.7	40.8	42.8	57.20
7	85	7.4	14.9	14.9	85.10
8	85	4.8	32.9	35.5	64.50
9	85	5.3	33.2	33.8	66.20
10	85	4.7	41.4	43.1	56.90
Minimum Filter Efficiency: 56.90			Maximum Filter Efficiency: 85.10		

- 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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Instructions



Open the small package of the product, put the side with nose clip on the mask upward, and hang the mask belt at both ends on both ears.



Open Cover the nose, mouth and chin with the protective mask, and press the nose clip lightly to make it fit the bridge of nose



Arrange the wearing effect of the mask to ensure the tightness of the mask

【Term of validity】 Three years

【Executive standard】 GB2626-2006

【Manufacturer Information】 See outside packaging box.

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[Main structure]

The utility model is composed of a mask body, a nose clip and a mask belt which are composed of a non-woven fabric and a folded ultrasonic wave.

[Instructions]

Cover the nose and mouth with the colored side of the mask. Hang the loop on the ear, adjust the curve of the film on the bridge of the nose to close to the bridge of the nose, and pull the mask down to cover the chin. Please discard after use.

[Product description]

The face mask is made of one or more kinds of nonwovens that can isolate virus-containing aerosol and liquids. Such face masks can still ward off virus-containing aerosol and liquids even under respiratory airflows, and the outer surface of the mask will not contact the human body when removed.

[Precautions]

1. Please read the instructions carefully before use, to confirm the package integrity, production date, and validity period of the face mask.
2. The face mask is for disposable use only; do not use it if the packaging is damaged.
3. Wash your hands before putting on a mask, or avoid touching the inside of the mask with your hands when you put on the mask, to reduce the possibility of the mask being contaminated.
4. Try to make the mask fit well as much as possible with your face. The simple test method to make sure that your mask fit well with your face is: exhale hard after putting on the mask, and no air can leak out from the edge of the mask.
5. Water washing will lose the protective effect.
6. Keep away from heat and direct sunlight.



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