

## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Qingdao Maysheng Medical Devices Co., Ltd.

Model Tested: KN95 Protective Mask (Self Suction Filter Respirator FFP2)

Date Tested: July 24, 2020

These findings pertain to the Qingdao Maysheng Medical Devices Co., Ltd., KN95 Protective Mask (Self Suction Filter Respirator FFP2). The packaging and labeling for this product indicate 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 98.36% and 95.07%, respectively. Ten 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 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 \(during known shortages\)](#).

## Evaluation of International Respirators

**Test:** Modified TEB-APR-STP-0059

**Date Tested:** July 24, 2020

**Report Prepared:** July 24, 2020

**Manufacturer:** Qingdao Maysheng Medical Devices Co., Ltd.

**Item Tested:** KN95 Protective Mask (Self Suction Filter Respirator FFP2)

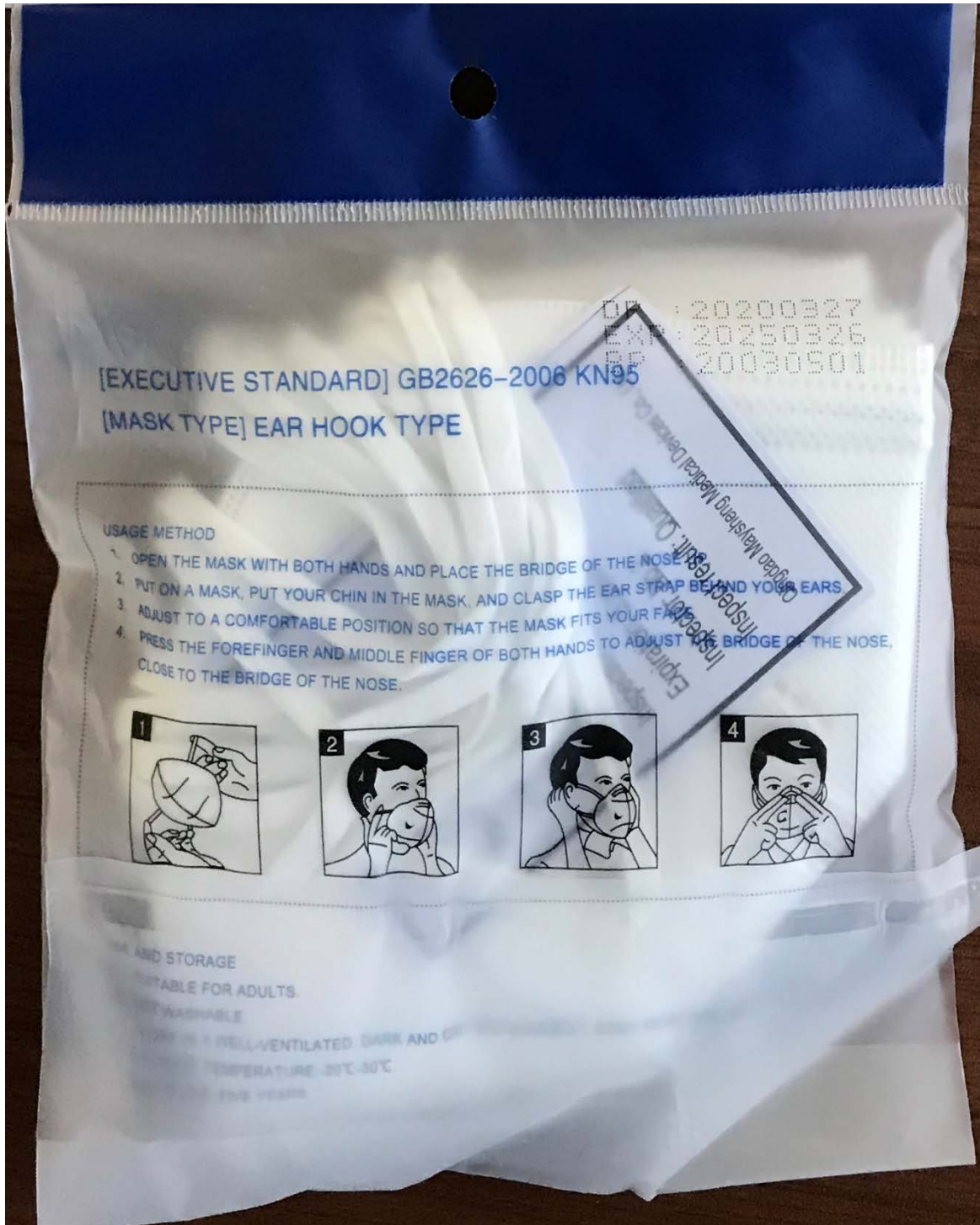
**Country of Certification:** China (GB2626-2006)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	13.5	4.58	4.58	95.42
2	85	12.9	4.60	4.60	95.40
3	85	17.3	3.36	3.36	96.64
4	85	13.9	4.93	4.93	95.07
5	85	8.4	1.71	2.31	97.69
6	85	12.3	4.84	4.84	95.16
7	85	8.2	3.10	3.97	96.03
8	85	10.4	1.14	1.65	98.35
9	85	9.1	1.14	1.64	98.36
10	85	7.1	1.57	2.22	97.78
<b>Minimum Filter Efficiency: 95.07</b>			<b>Maximum Filter Efficiency: 98.36</b>		

- 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.





[EXECUTIVE STANDARD] GB2626-2006 KN95  
[MASK TYPE] EAR HOOK TYPE

DN : 20200327  
EXP : 20250326  
SP : 20030501

USAGE METHOD

1. OPEN THE MASK WITH BOTH HANDS AND PLACE THE BRIDGE OF THE NOSE STRAP BEHIND YOUR EARS
2. PUT ON A MASK, PUT YOUR CHIN IN THE MASK AND CLASP THE EAR STRAP BEHIND YOUR EARS
3. ADJUST TO A COMFORTABLE POSITION SO THAT THE MASK FITS YOUR FACE
4. PRESS THE FOREFINGER AND MIDDLE FINGER OF BOTH HANDS TO ADJUST THE BRIDGE OF THE NOSE, CLOSE TO THE BRIDGE OF THE NOSE.



USE AND STORAGE

SUITABLE FOR ADULTS  
REUSABLE  
STORE IN A WELL-VENTILATED DARK AND DRY PLACE  
TEMPERATURE -20°C-30°C  
USE FOR 5-6 YEARS

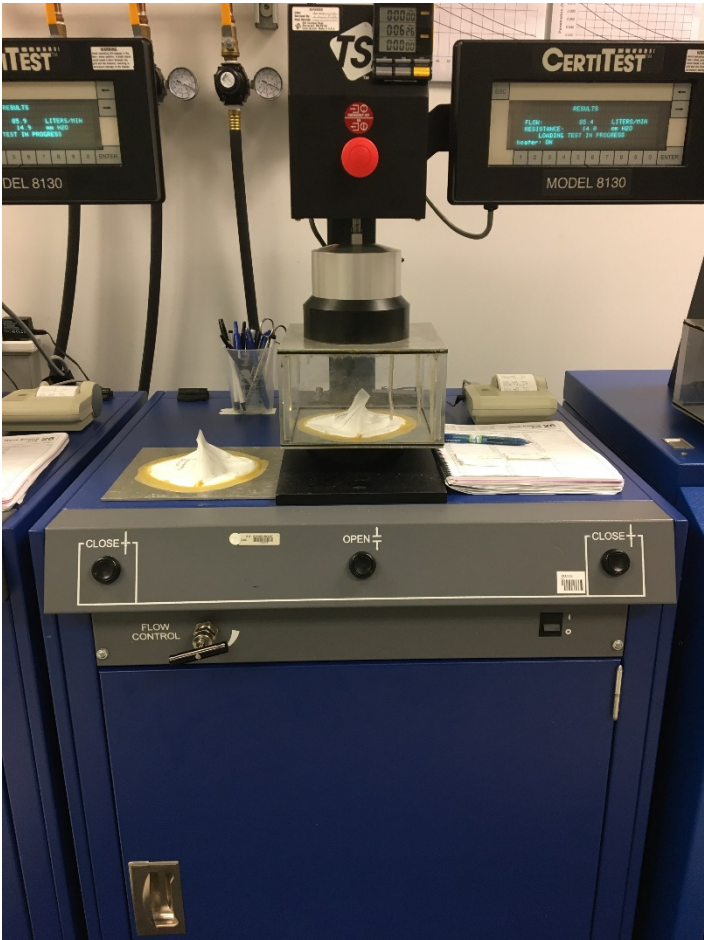
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