NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Wenzhou Meiyi Medical Device Co., Ltd.
Model Tested: MY-002
Date Tested: June 4, 2020

These findings pertain to the Wenzhou Meiyi Medical Device Co., Ltd., model MY-002. The packaging for this product indicates t hat 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 94.54% and 35.60%, 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

NPPTL
National Personal Protective Technology Laboratory

Test: Modified TEB-APR-STP-0059

Date Tested: June 4, 2020

Report Prepared: June 4, 2020

Manufacturer: Wenzhou Meiyi Medical Device Co., Ltd.

Item Tested: MY-002

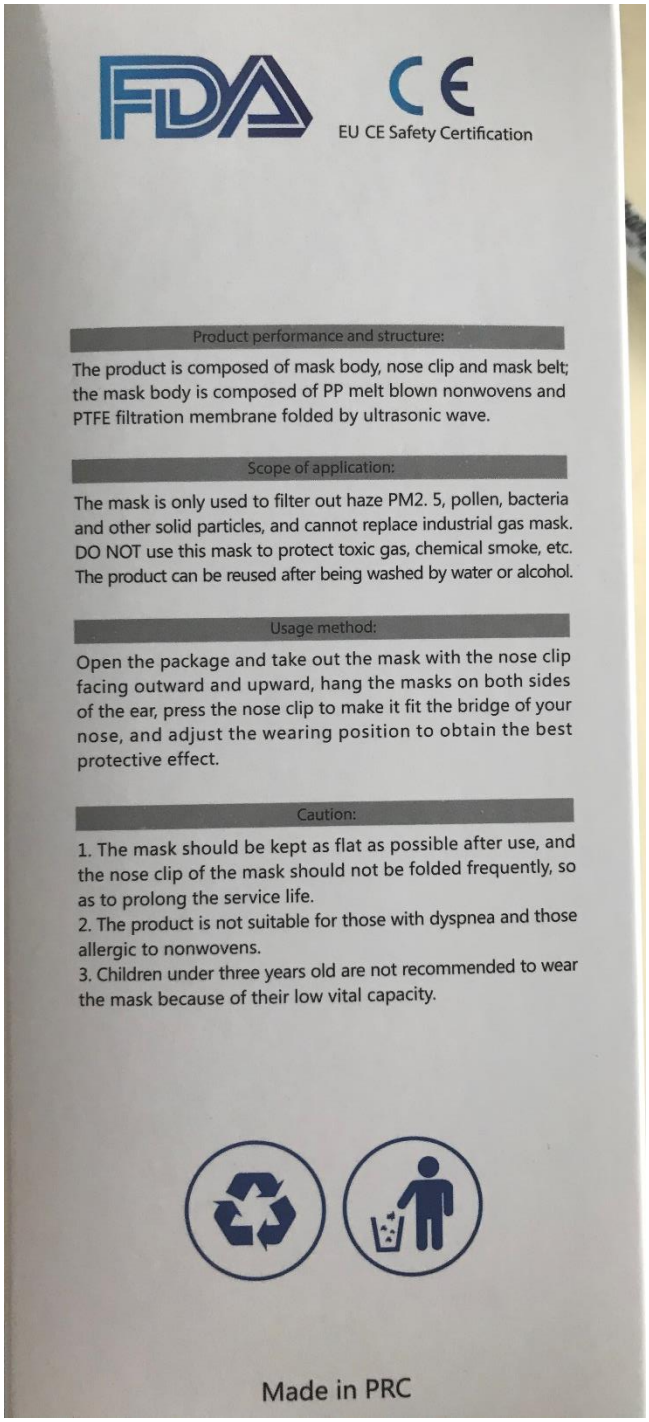
Country of Certification: China (GB2626-2006, EN149:2001+A1:2009)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	6.7	8.56	9.43	90.57
2	85	6.4	60.4	64.4	35.60
3	85	9.1	5.46	5.46	94.54
4	85	7.5	7.85	8.29	91.71
5	85	6.5	13.1	14.3	85.70
6	85	5.3	25.66	26.28	73.72
7	85	5.7	15.0	17.8	82.20
8	85	6.0	13.8	15.2	84.80
9	85	5.6	22.36	22.72	77.28
10	85	6.4	16.56	17.30	82.70
Minimum Filter Efficiency: 35.60			**Maximum Filter Efficiency: 94.54**		

- 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.


RYK
Conforms to standard GB2626-2006 Kn95 standard
Conforms to standard EN 149:2001+AI-2009 FFP2 standard
3D FACIAL PROTECTIVE MASK
Four-in-one function of Anti-haze, sterilization, antivirus, formaldehyde removal
Technology bacteriostatics and antibacterial TECH
Health originates from technology!
PTFE membrane filtration with the bacteria
Resistance rate up to 95%
It can be recycled for 20 times
16pcs


FDA
CE
EU CE Safety Certification
Product performance and structure:
The product is composed of mask body, nose clip and mask belt; the mask body is composed of PP melt blown nonwovens and PTFE filtration membrane folded by ultrasonic wave.
Scope of application:
The mask is only used to filter out haze PM2. 5, pollen, bacteria and other solid particles, and cannot replace industrial gas mask. DO NOT use this mask to protect toxic gas, chemical smoke, etc. The product can be reused after being washed by water or alcohol.
Usage method:
Open the package and take out the mask with the nose clip facing outward and upward, hang the masks on both sides of the ear, press the nose clip to make it fit the bridge of your nose, and adjust the wearing position to obtain the best protective effect.
Caution:
1. The mask should be kept as flat as possible after use, and the nose clip of the mask should not be folded frequently, so as to prolong the service life.
2. The product is not suitable for those with dyspnea and those allergic to nonwovens.
3. Children under three years old are not recommended to wear the mask because of their low vital capacity.
Made in PRC


RYK
Model:MY-002
Executive standard:Q/HMT 001-2020
Storage conditions: it should be placed in a cool and dry place.
Date of manufacture: see the inkjet code.
Shelf life: three years(sealed)
Manufacturer: Wenzhou Meiyi medical device CO.,Ltd.
Address: Hengjie Industrial , Xianjiang Street , Ruian Wenzhou , Zhejiang , China
Made in PRC
MA
CNAS
WENZHOU MEIYI MEDICAL DEVICE CO.,LTD.

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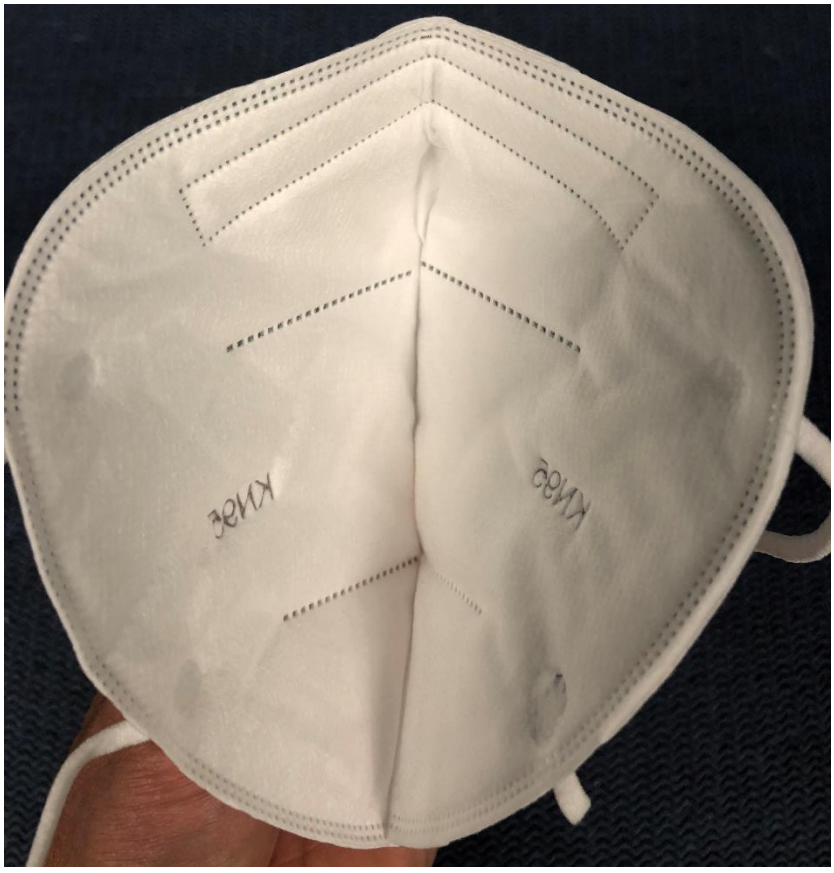

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