

## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Hunan Youhong Medical Technology Co., Ltd.

Model Tested: YH006

Date Tested: September 10, 2020

These findings pertain to the Hunan Youhong Medical Technology Co., Ltd., model YH006. The packaging for this product indicates that it meets 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 98.23% and 93.52%, respectively. Seven respirators measured more than 95%. Three 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:** September 10, 2020

**Report Prepared:** September 11, 2020

**Manufacturer:** Hunan Youhong Medical Technology Co., Ltd.

**Item Tested:** YH006

**Country of Certification:** European (EN149:2001+A1:2009)

Pictures have been added to the end of this report.

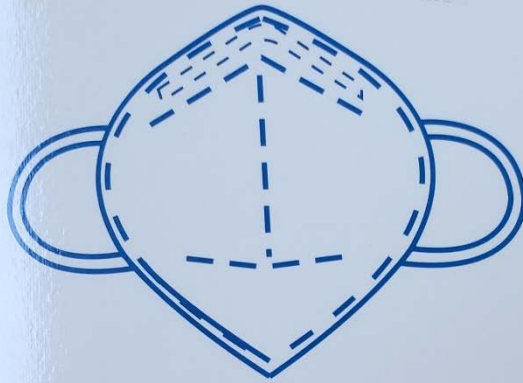
Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	6.8	3.17	3.27	96.73
2	85	7.8	5.51	6.28	93.72
3	85	6.2	1.75	1.77	98.23
4	85	8.0	4.96	5.12	94.88
5	85	8.4	6.20	6.48	93.52
6	85	5.7	4.24	4.33	95.67
7	85	8.7	3.83	3.96	96.04
8	85	8.1	2.91	2.99	97.01
9	85	7.7	2.98	2.99	97.01
10	85	6.0	4.49	4.53	95.47
<b>Minimum Filter Efficiency: 93.52</b>			<b>Maximum Filter Efficiency: 98.23</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.

Model: YH006

# Face Respirator

FFP2



- Foldable 3D structure design for better protection
- Bacterial Filtration Efficiency (BFE)  $\geq 95\%$

160 mm x 107 mm

**50 PCS**

# Face Respirator

FFP2

**Product name:** Face Respirator

**Model:** YH006

**Size:** 160 mm x 107 mm

**Bacterial Filtration Efficiency (BFE)  $\geq$  95%**

**Qty:** 50 pieces

**Structure:** mask body, adjustable nose clip and earloop

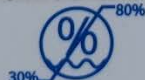
**Main Materials:**

**Inner layer:** Polypropylene hot-rolled non-woven fabric

**Middle layer:** Polypropylene melt-blown non-woven fabric

**Outer layer:** Polypropylene spunbond non-woven fabric

EN 149 : 2001+ A1 :2009 / FFP2

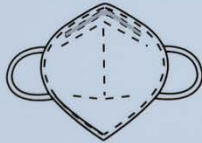


## Instructions for use:

1



2



3



4



1. Hold the mask with your fingertips in the nose clip position, and slowly open the mask
2. Attach the mask on the face with the nose clip above, and press the nose clip to ensure the tightness of the mask.
3. Hang the earloop around your ears and adjust the length of the earloop for more comfortable wearing.
4. Breathe quickly to check if air leakage from the nose, then readjust the nose clip and ear loop with the mask tightly to the face.

### Note:

- These masks are single use only/ disposable. Re-use or extended use may lead to infection or cross contamination.
  - The mask should be stored in a cool, dry place.
- Avoid excessive heat.

### Batch Code:

Validity period: 24 months.

04/11/2020

Made in China



## NPPTL COVID-19 Response: International Respirator Assessment

FDA Registration Number: 3009707582

Product: Face Respirator

Model: YH006

Intended Use: Used in a health care setting by health care professionals.

Final Disposition: General

Classification Name: RESPIRATOR

Product Code: MSH

Regulation Number: 878.4040

Exporter: Joint Chinese Ltd

Address: Building 4&6, Huafeng Technology Park,  
Guangtian Road, 3rd Industrial Zone, Luotian Community,  
Yanluo Stress, Bao'an District, Shenzhen City, Guangdong,  
China, 518125

Manufacturer: Hunan Youhong Medicial Technology Co.,Ltd

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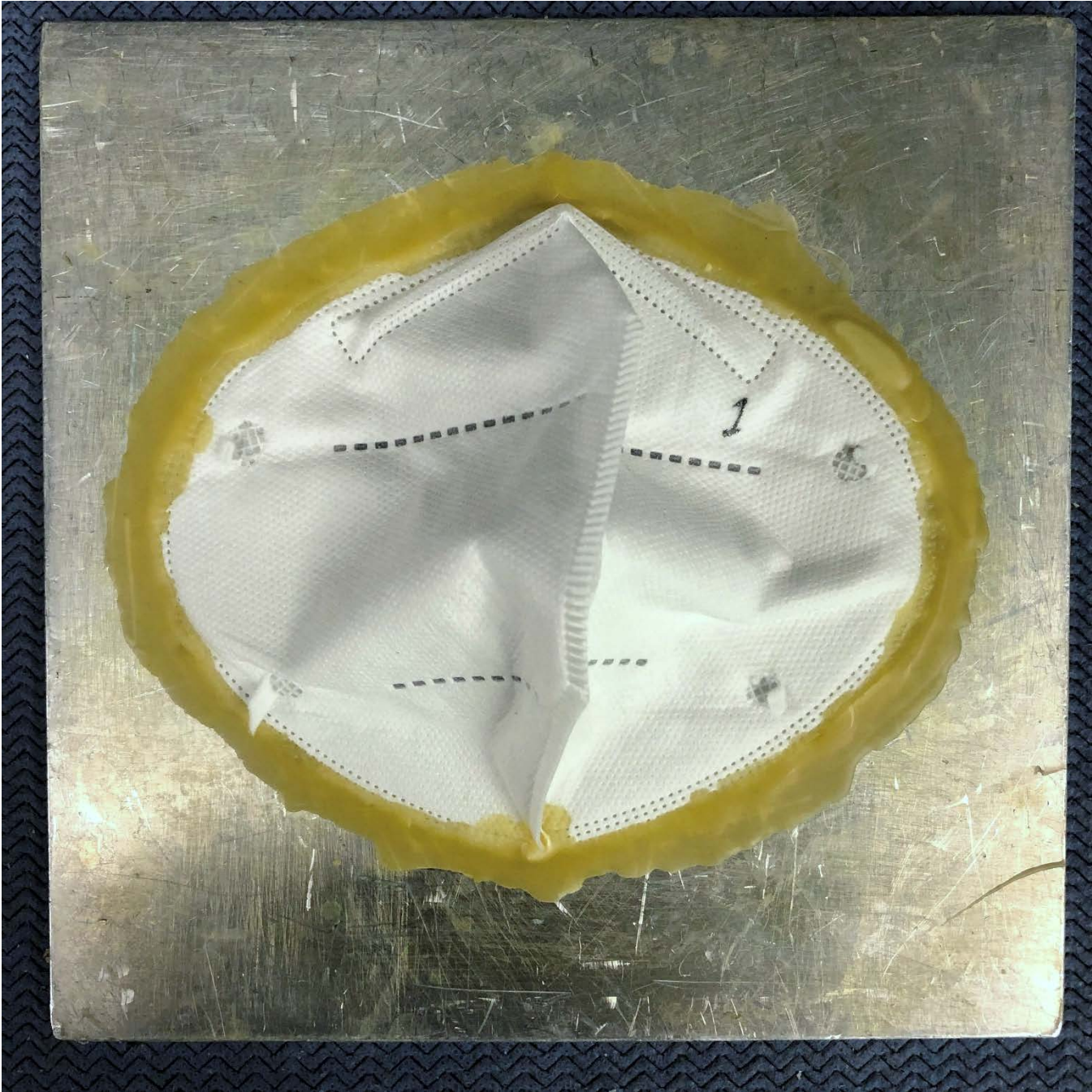


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