

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Hunan Youhong Medical Technology Co., Ltd.

Model Tested: N95-YH006

Date Tested: September 10, 2020

These findings pertain to the Hunan Youhong Medical Technology Co., Ltd., Model N95-YH006. The packaging for these respirators indicates they meet GB19083-2010 (the Chinese standard for Technical Requirements for Protective Face Mask for Medical Use).

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 98.02% and 89.20%, respectively. Five respirators measured more than 95%. Five 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 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: September 10, 2020

Report Prepared: September 11, 2020

Manufacturer: Hunan Youhong Medical Technology Co., Ltd.

Item Tested: N95-YH006

Country of Certification: China (GB19083-2010)

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 | 7.8 | 8.39 | 8.39 | 91.61 |
| 2 | 85 | 6.8 | 8.14 | 8.39 | 91.61 |
| 3 | 85 | 6.3 | 6.78 | 6.93 | 93.07 |
| 4 | 85 | 20.2 | 3.14 | 3.14 | 96.86 |
| 5 | 85 | 6.0 | 4.32 | 4.42 | 95.58 |
| 6 | 85 | 6.2 | 6.79 | 6.97 | 93.03 |
| 7 | 85 | 7.4 | 10.3 | 10.8 | 89.20 |
| 8 | 85 | 11.0 | 3.98 | 4.07 | 95.93 |
| 9 | 85 | 15.7 | 1.98 | 1.98 | 98.02 |
| 10 | 85 | 6.9 | 2.47 | 2.55 | 97.45 |
| Minimum Filter Efficiency: 89.20 | | | Maximum Filter Efficiency: 98.02 | | |

- 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.



Face Respirator

N95 Respirator MSH Class 2 | Not a NIOSH Product

Product name: Disposable Face Mask | Model: N95-YH006

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

Size: 6.3" x 4.2" | Product Code: MSH | Qty: 50 pieces

Standard: GB19083-2010 | Validity: 2 Years

Regulation Number: 878.4040

Exporter: Joint Chinese LTD

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

Product Performance:

1. Bacterial Filtration Efficiency $\geq 95\%$
2. Product is registered by the FDA in USA
3. Not a NIOSH product

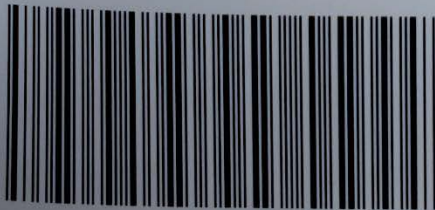
Address: East Xingfuqu Road, Changchun Economic Development
Zone, Ziyang District, Yiyang, Hunan, China

Manufacturer:

Hunan Youhong Medical Technology Co., Ltd

Manufacture date: See qualification certificate inside the gift box

Batch code: See qualification certificate inside the gift box



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Instructions for use:



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.

Made in China



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产品合格证
Product Qualification Certificate

产品名称(Product Name): 医用防护口罩 (非无菌型)
Medical Protective Mask(Non-sterile)

型号(Model#): N95- YH006

规格 (Specification): 长160mm × 宽107mm

结构 (Structure): 口罩体, 鼻夹, 口罩带
(mask body, adjustable nose clip and earloop)

原材料 (Raw Materials): 无纺布62%, 熔喷布38%
(62% non-woven fabric, 38% Melt-blown fabric)

执行标准(Standard): GB19083-2010

数量(Quantity): 50PCS

有效期 (Validity): 2年 (2 Years)

检验员代码 (Inspector ID): YHQC-03

生产批次(Batch No.): 200461

生产日期 (Production Date):

湖南友宏医疗科技有限公司
Hunan Youhong Medical Technology Co., Ltd
湖南省益阳市资阳区长春经济开发区幸福渠东路
East Xingfuqu Road, Changchun Economic Development Zone,
Ziyang District, Yiyang, Hunan, China

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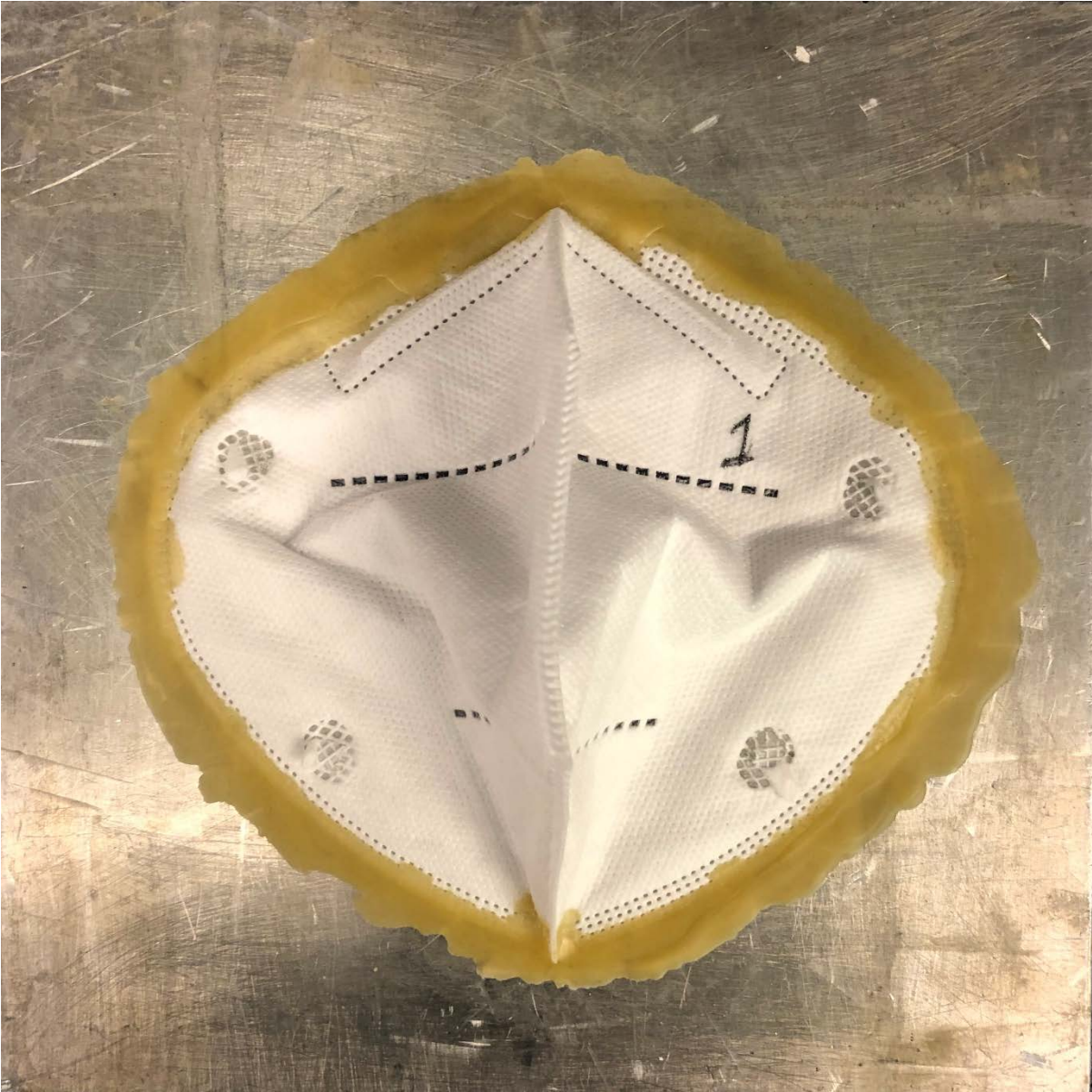
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检验合格章



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