

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Hunan YuanKang Biological Technology Co, Ltd.

Model Tested: N95 (closed arch MA type)

Date Tested: September 9, 2020

These findings pertain to the Hunan YuanKang Biological Technology Co, Ltd., model N95 (closed arch MA type). The packaging and labeling 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 98.27% and 91.46%, respectively. Eight respirators measured more than 95%. Two 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 9, 2020

Report Prepared: September 9, 2020

Manufacturer: Hunan YuanKang Biological Technology Co, Ltd

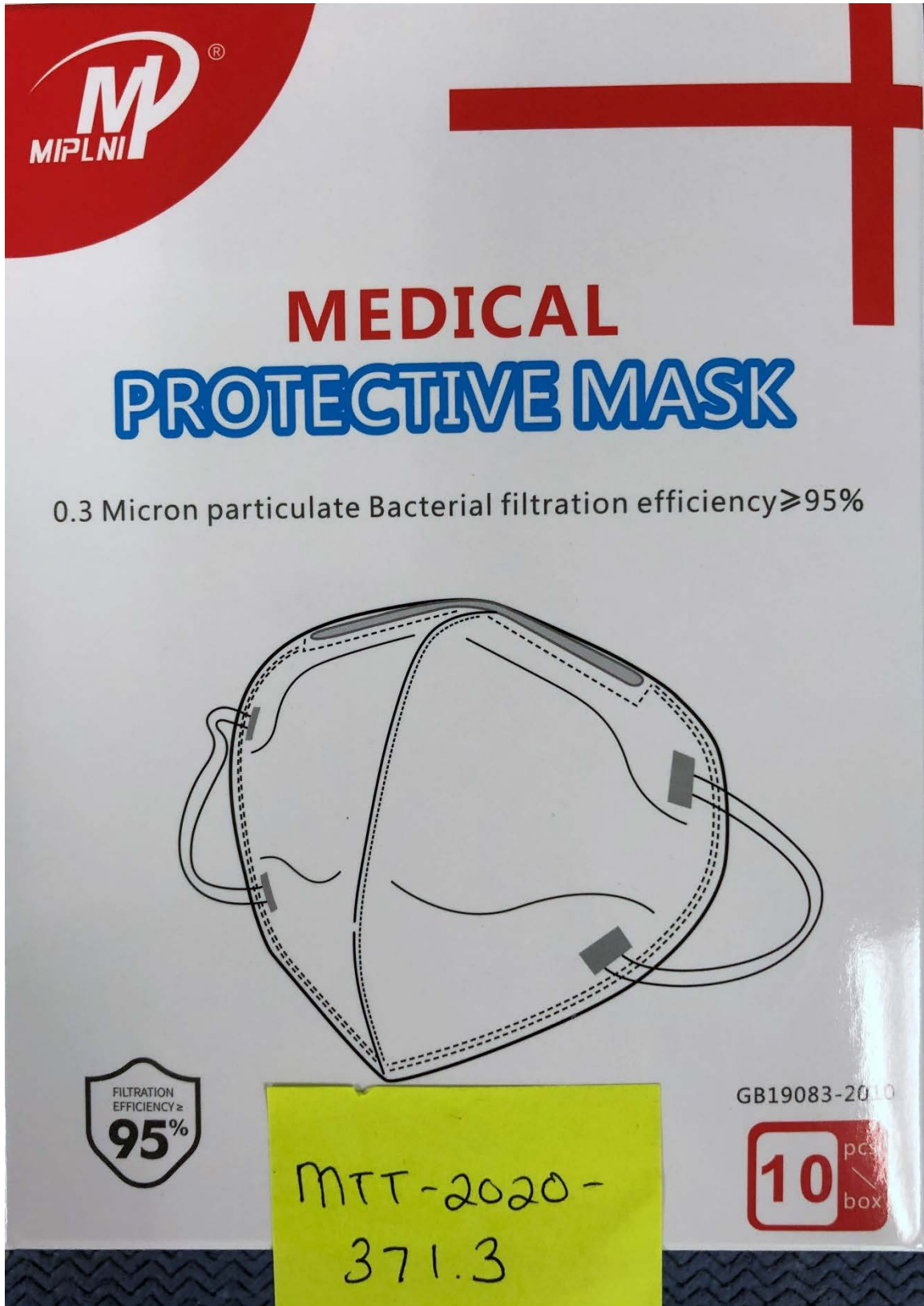
Item Tested: N95 (closed arch MA type)

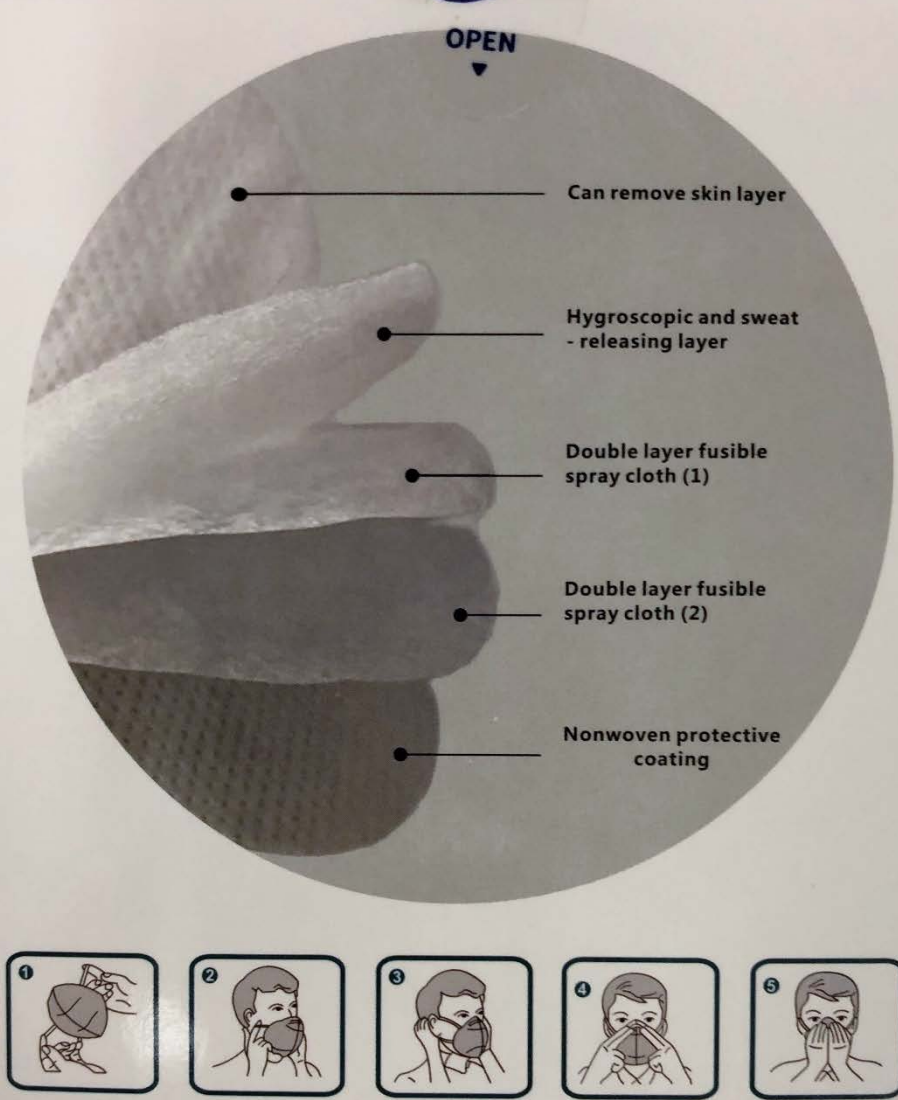
Country of Certification: China (GB19083-2010)

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	11.0	4.04	4.04	95.96
2	85	9.7	8.14	8.54	91.46
3	85	9.5	3.12	3.12	96.88
4	85	10.3	2.09	2.09	97.91
5	85	9.2	1.73	1.73	98.27
6	85	12.1	4.03	4.03	95.97
7	85	9.6	2.99	2.99	97.01
8	85	10.1	4.23	4.33	95.67
9	85	11.1	5.19	5.19	94.81
10	85	9.5	2.82	2.82	97.18
Minimum Filter Efficiency: 91.46			Maximum Filter Efficiency: 98.27		

- 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.





OPEN

- Can remove skin layer
- Hygroscopic and sweat - releasing layer
- Double layer fusible spray cloth (1)
- Double layer fusible spray cloth (2)
- Nonwoven protective coating

- 1
- 2
- 3
- 4
- 5

Wearing methods and precautions of Protective mask

【instructions】 spread the mask, pull both hands towards the face, hold the mask with the left hands, wrap the rope around the ear with the right hand, hold the mask with the right hand, wrap the rope around the ear with the left hand, pull the edge of the mask with both hands up and down, cover the face and chin.



[Structure and composition] the medical respirator(not-sterile)consists of the mask body,nose clip and ear band.The inner layer of the mask is made of non-woven fabric,the inter layer is made of ultra-fine polypropylene filter cloth,the nose clip is made of flexible aluminum material,and the ear band is made of elastic band(nylon+spandex).

[application] :applicable to the protection of medical staff and related staff against airborne respiratory infectious diseases.It should not be used for isolation of critical car areas(rooms) and other places with strict control microbial indicators.

[Precautions,warning,and instructions] ① Use this product correctly in accordance with the instructions; ② Only for onetime use,destroy after use; ③ prohibited to use when package is damaged . ④ prohibited to use when the product exceeds the expiration date.

[Storage conditions and methods] The product should be stored in a room with <80% humidity,no corrosive gas and good ventilation.

[Performance indicators] The products meet the requirements of GB 19083-2010 for medical protective masks. FILTRATION EFFICIENCY: under the condition of 85L/Min Gas flow rate,the filtration efficiency of respirator to non-oil particles should not be less than 95%.

[Product name]medical protective mask (not sterile)

[Model]N95(Closed arch MA type)

[Company Name]Hunan YuanKang Biological Technology Co.,Ltd

[Production Address] Beside provincial Highway S315,Luojia Group, Dachuan Village,Yanpi Town,Hengyang County,Hunan Province

PC20200324 MFG 2020/05/14
EXP 2022/05/13

[Production license no] Xiang food and drug supervision machinery production Licence No.20200013

[Medical Device Registration Certificate No.] Xiang Machinery Registration No. 20202140871

[Production batch]

[production date]

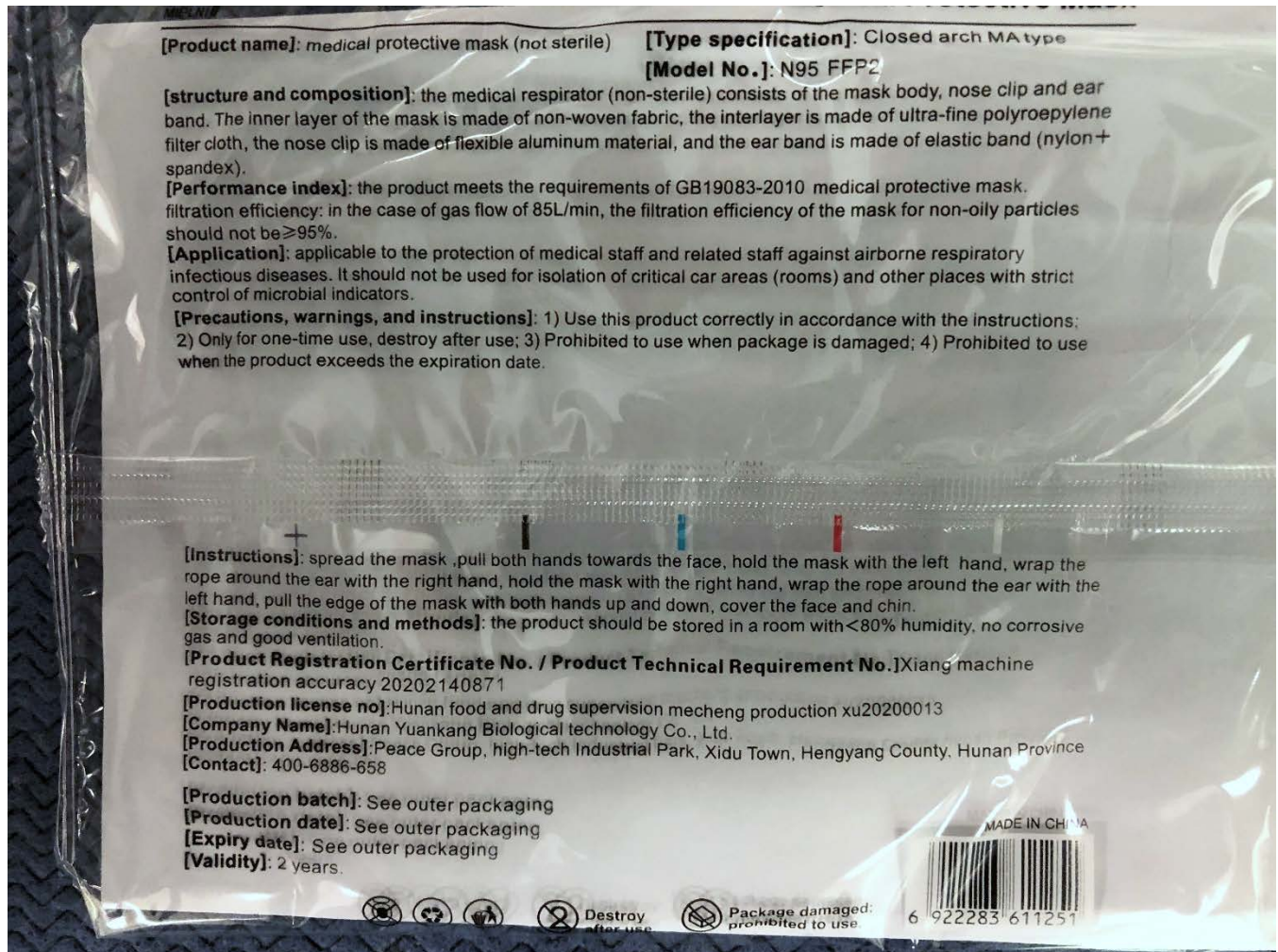
[Expiry date]

[Validity]two years

[Contact]400-6886-658

Made in China

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