

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: ORICH Medical Equipment (Tianjin) Co., Ltd.

Model Tested: N95

Date Tested: March 1, 2021

These findings pertain to the ORICH Medical Equipment (Tianjin) Co., Ltd., model N95. The packaging for this product indicates 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 99.15% and 77.10%, respectively. Five respirators measured more than 95% filter efficiency. Five respirators measured less than 95% filter efficiency.

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: March 1, 2021

Report Prepared: March 1, 2021

Manufacturer: ORICH Medical Equipment (Tianjin) Co., Ltd.

Item Tested: N95

Country of Certification: China (GB2626-2006)

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	8.5	6.26	7.51	92.49
2	85	15.2	2.80	2.85	97.15
3	85	9.2	7.45	7.58	92.42
4	85	13.9	4.24	4.24	95.76
5	85	6.8	21.5	22.9	77.10
6	85	9.7	14.3	14.5	85.50
7	85	9.6	3.30	3.30	96.70
8	85	8.1	20.4	20.7	79.30
9	85	16.4	1.03	1.03	98.97
10	85	14.2	0.85	0.85	99.15
Minimum Filter Efficiency: 77.10%			Maximum Filter Efficiency: 99.15%		

- 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.



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Application:

This product is worn by all kinds of people in production and life, covering the mouth, nose and jaw of users, to prevent PM2.5, dust, formaldehyde, automobile exhaust, industrial dust, bacteria and viruses directly through the provision of a protective barrier.

Storage conditions and Methods:

Store in a room with relative humidity no more than 80% and temperature between - 20 ° C and 50 ° C, free of corrosive gas and well ventilated, and away from pollution sources.

Structure and Composition:

The mask is composed of a mask body, a nose clip and a mask belt.

This product is a non-medical device.

Contraindications:

1. Allergic to the material of this product are prohibited to use.
2. For severe asthma and other severe respiratory disease

Other details can be found in the instruction manual

【Product name】 N95 mask

【Model and Specification】 N95 160mmX105mm

【Raw material and Proportion】 non-woven fabric 44%, meltblown fabric 28%, hot air cotton 28%.

【Service life】 Three years since the production date

【No. Per Unit】 5pcs/ box

【Protection level】 Filter for non oily particles $\geq 95\%$

【Production date】 shown box

【Lot No. 】 shown box

【Manufacturer】 ORICH Medical Equipment (Tianjin) Co.,Ltd

【Address】 South Area, D block, No.16 Cuiming Road,
YAT-SEN Scientific Industrial Park, TEDA, Tianjin.

【After-sales service Unit】 ORICH Medical Equipment (Tianjin) Co.,Ltd.

【Tel】 +86400-6850-899

【Website】 [http:// www.orich.com.cn](http://www.orich.com.cn)

Other details information please check the instruction

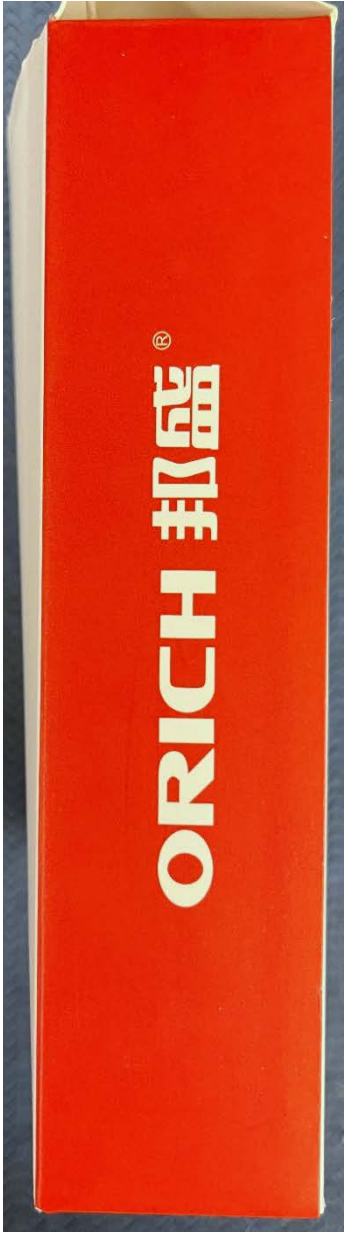
Made in China



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生产日期:2020.05.02

生产批号:NFO420001



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ORICH 邦盛®

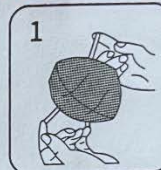
N95
MASK **5 pcs**

This product is a non-medical device.
 [Scope of application] This product is worn by all kinds of people in production and life, covering the mouth, nose and jaw of users, to prevent PM2.5, dust, formaldehyde, automobile exhaust, industrial dust, bacteria and viruses directly through the provision of a protective barrier
 [Structure and composition] The mask is composed of a mask body, a nose clip and a mask belt.

- [Contraindications]
1. Allergic to the material of this product are prohibited to use
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[Product name] N95 mask
 [Model and Specification] N95 160mmX105mm
 [Raw material and Proportion] non-woven fabric 44%, meltblown fabric 28%, hot air cotton 28%
 [Service life] Three years since the production date
 [No. Per Unit] 5pcs/ bag
 [Protection level] Filter for non oily particles ≥ 95%
 [Production date] shown box
 [Lot No.] shown box
 [Manufacturer] ORICH Medical Equipment (Tianjin) Co., Ltd
 [Address] South Area, D block, No.16 Cuiming Road, YAT-SEN Scientific Industrial Park, TEDA, Tianjin.
 [Tel] +86400-6850-899 [Postal code] 301700
 [Website] <http://www.orich.com.cn>
 Made in China

Wearing Method



1 Pull the elastic band to the back of the ear, adjust the mask and elastic band to feel comfortable.



2 Cover the mask with your hands and exhale. If any gas leaks from the edge of the mask, adjust the mask again until no gas leaks.



3 Adjust the elastic belt to the comfortable position.



4 Adjust the bridge of nose to make the mask fit the bridge of nose and cheek closely.

Other details can be found in the instruction manual



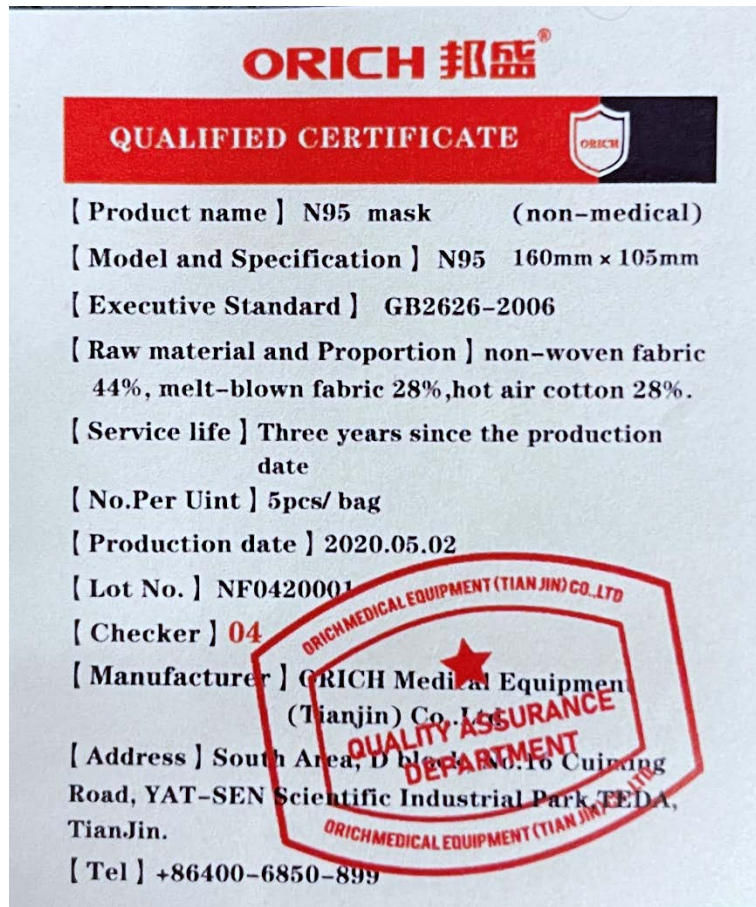
Precautions, warnings and tips

1. Check the package before use. It is forbidden to use if the package is damaged.
2. Confirm the validity period of the product before use, and use it within the validity period.
3. This product is disposable and cannot be reused.
4. If it is dirty, please replace it in time.
5. Please stop using in case of skin abnormality or discomfort.
6. Do not use the nose clip with one hand, otherwise it will cause sharp angle of nose clip, cause leakage, and reduce the mask function. The nose clips should be pressed with both hands.
7. This product is non-sterile.

[Storage conditions and methods] Store in a room with relative humidity no more than 80% and temperature between -20° C and 50° C, free of corrosive gas and well ventilated, and away from pollution sources.
 Executive Standard GB2626-2006

One time use

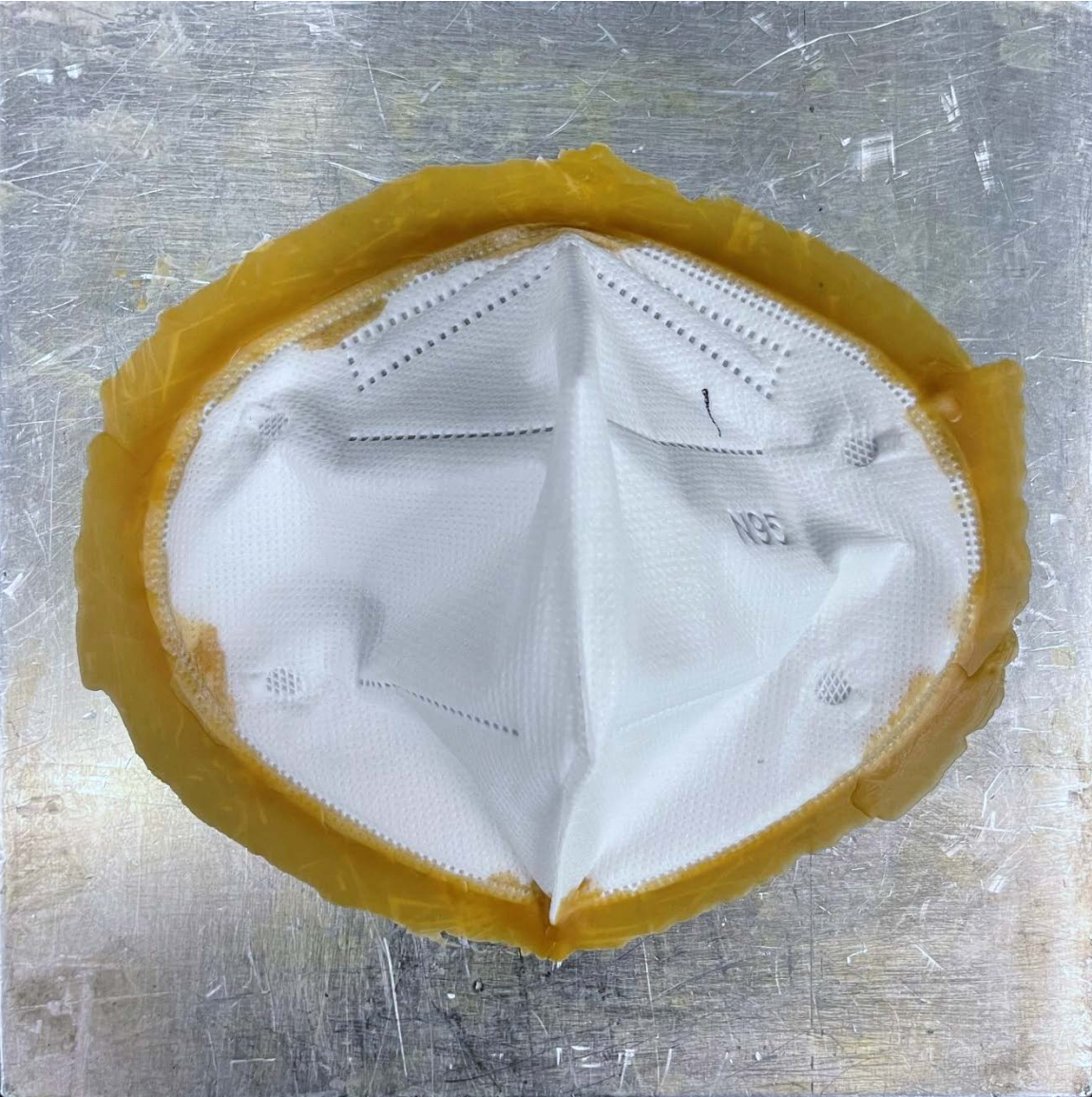




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