

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: UNKNOWN

Model Tested: 9001

Date Tested: June 17, 2020

These findings pertain to the UNKNOWN, model 9001. The packaging and labeling for this product indicate that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Thirty respirators were submitted for evaluation. Only ten respirators were requested, so, the decision was made to test twenty. 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 98.88% and 96.48%, respectively. All twenty respirators measured more 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: June 17, 2020

Report Prepared: June 17, 2020

Manufacturer: UNKNOWN

Item Tested: 9001

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	10.9	2.32	2.32	97.68
2	85	24.2	1.37	1.37	98.63
3	85	12.9	2.70	2.70	97.30
4	85	11.0	3.51	3.51	96.49
5	85	10.9	2.64	2.69	97.31
6	85	13.6	2.20	2.20	97.80
7	85	14.0	2.27	2.27	97.73
8	85	11.8	3.36	3.36	96.64
9	85	14.9	2.83	2.83	97.17
10	85	23.4	2.19	2.19	97.81
Minimum Filter Efficiency: 96.49			Maximum Filter Efficiency: 98.63		

- 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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Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
11	85	13.6	1.62	1.62	98.38
12	85	14.2	1.53	1.53	98.47
13	85	12.8	2.51	2.51	97.49
14	85	10.9	1.12	1.12	98.88
15	85	23.4	2.56	2.56	97.44
16	85	12.3	3.23	3.23	96.77
17	85	11.0	3.52	3.52	96.48
18	85	12.3	2.18	2.18	97.82
19	85	12.6	2.30	2.30	97.70
20	85	13.3	2.58	2.58	97.42
Minimum Filter Efficiency: 96.48			Maximum Filter Efficiency: 98.88		

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Detail

This KN95 particulate respirator has comfortable inner materials and helps provide respiratory protection against certain airborne particles.

This KN95 respirator is designed to help provide respiratory protection for the wearer. As a disposable particulate respirator, it is intended to reduce wearer exposure to certain airborne particles.

Removal Instructions:

Without touching the respirator, slowly lift both straps from your ears. Fold the mask away from your face. Store or discard according to your facility's infection control policy. Dispose of used product in accordance with applicable regulations.

Cautions and Limitation:

1. Not for use in atmospheres containing less than 19.5 percent oxygen.
 2. Not for use in atmospheres immediately dangerous to life or health.
 3. Do not exceed maximum use concentrations established by regulatory standards.
 4. Failure to properly use this product could result in injury or death.
 5. Never adjust, fix, modify, weld, or trim parts. Use only exact replacement parts to the configuration as specified by the manufacturer.
 6. Not for use with beards or other facial hair or conditions that prevent a good seal between the face and the sealing edge of the respirator.
 7. This respirator was not designed to be used by children.
- Not for use in environment that the temperature is over 50°C

Storage Conditions and Shelf Life:

Before use store respirators in the original packaging, away from contaminants, areas with sunlight, extreme temperatures, excessive moisture and damaging chemicals.

When stored in original packaging between temperatures from -4°F (-20°C) to 140°F (60°C) and not exceeding 65% RH. The original product is valid for three years from the date of production.



Instruction:

1. Wash hands before putting on a mask, before and after taking one off.
2. The nose clip part is outward, with the metallic strip upward.
3. Push the mask against the chin first, bend the elastic straps at both ears to properly fit. Keep the mask firmly in place.
4. Tilt one side of respirator to further adjust. Breathe for a comfortable fit as necessary. Make certain hair, facial hair, jewelry and clothing are not between your face and the respirator so they will interfere with fit. Make certain respirator is completely opened and adjust to fit against your face.
5. Place your fingertips from both hands on the top of the nose bridge. Use both hands to bend the nose bridge to fit snugly against your nose and face. Slide fingers down both sides of the nose bridge to seal it against your nose and face. Pinching the nosepiece using one hand may result in improper fit and less effective respirator performance. (See Test Series.)
6. Perform a User Seal Check. To check the respirator-to-face seal, cover both hands completely over the respirator and inhale. Be careful not to disturb the position of the nosepiece. If air leaks around the nose, re-adjust the nosepiece as described in step 5. If air leaks around respirator edges, adjust position of straps and make certain respirator edges fit snugly against the face.

IMPORTANT

Before use, wearer must read and understand these User Instructions.
Keep these User Instructions for reference.

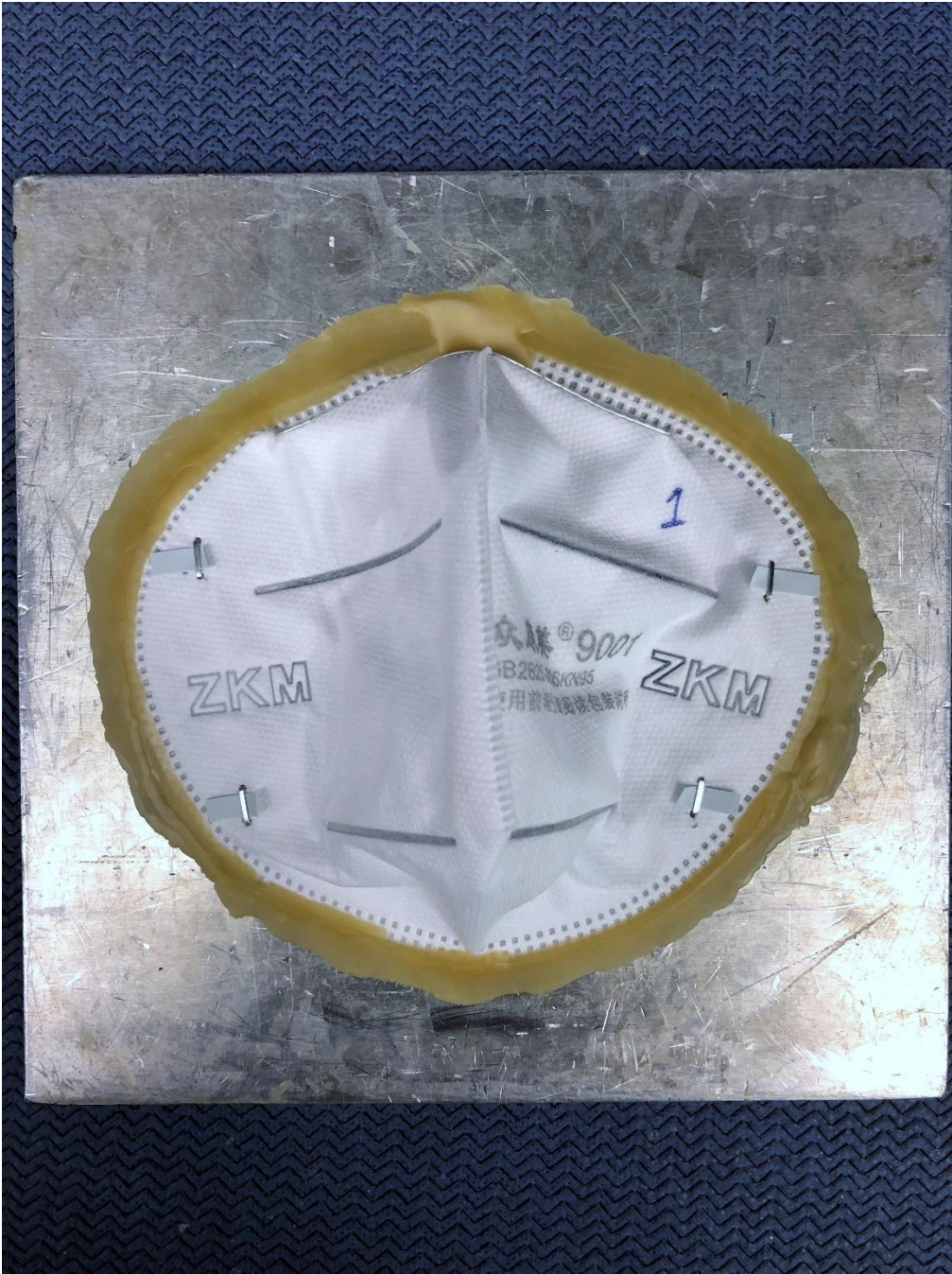
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