

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Xiantao Zhong Yi Safety & Protection Products Co., Ltd.

Model Tested: ZYB II

Date Tested: May 28, 2020

These findings pertain to the Xiantao Zhong Yi Safety & Protection Products Co., Ltd., model ZYB II. The packaging and labeling for this product indicates that it is a NIOSH-approved product, under approval number TC-84A-7577.

Forty respirators were submitted for evaluation. However, since these are NIOSH-approved respirators, only ten samples were tested. Samples 1-5 were from the container labeled 1B42 and samples 6-10 were from the container labeled 1B40. 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](#).

The maximum and minimum filter efficiency was 99.82% and 99.12%, respectively. All ten respirators measured more than 95%.

This product has head bands/straps. 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: May 28, 2020

Report Prepared: May 29, 2020

Manufacturer: Xiantao Zhong Yi Safety & Protection Products Co., Ltd.

Item Tested: ZYB II

Country of Certification: USA (42 CFR 84)

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	15.4	0.54	0.55	99.45
2	85	16.2	0.18	0.18	99.82
3	85	16.1	0.18	0.19	99.81
4	85	15.5	0.27	0.29	99.71
5	85	15.5	0.30	0.30	99.70
6	85	12.3	0.62	0.71	99.29
7	85	12.5	0.60	0.69	99.31
8	85	12.3	0.75	0.88	99.12
9	85	12.5	0.57	0.71	99.29
10	85	12.4	0.59	0.78	99.22
Minimum Filter Efficiency: 99.12			Maximum Filter Efficiency: 99.82		

- 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.



DONNING & FITTING INSTRUCTIONS

Follow these instructions each time respirator is worn.



1. Adjust the elastic straps for suitable size before placing the respirator on the face.



2. Cup the respirator in your hand, with nose piece towards your fingers.



3. Position the respirator at mouth and nose. Pull the elastic strap near your hand over your head resting it at the back of your head. Pull the strap near your finger over your head and position it at the top of your head and adjust the elastic straps.



4. Shape the nose piece suitably with your forefingers and middle fingers in order to keep the respirator to cling your face.



5. Use two hands perform seal check prior to each wearing. To check fit, place both hands completely over the respirator and exhale. Be careful not to disturb the position of the respirator. If air leaks around nose, readjust the nosepiece as described in step 4. If air leaks at the respirator edges, work the straps back along the sides of your head. If you CANNOT achieve a proper fit, DO NOT enter the contaminated area. See your supervisor.

FIT-CHECK THE FACE-SEAL AS FOLLOWS:

- place both hands completely over the respirator;
- exhale sharply;
- if air leaks around nose, readjust the nosepiece as described in step 4. If air leaks at the respirator edges, work the straps back along the sides of your head.

The respirator must be used in accordance with OSHA regulations

29 CFR 1910.134 which includes the requirement for fit testing before use.

WARNING: If you cannot achieve satisfactory fit, do NOT enter the contaminated area.

CAUTION:

The straps on the respirator are completely latex-free. Individuals who are highly sensitive to natural rubber latex can be easy to use.

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USE INSTRUCTIONS:

1. Failure to follow all instructions and limitations on the use of this respirator and/or failure to wear this respirator during all times of exposure can reduce respirator effectiveness and may result in sickness or death.
2. Before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the requirements of OSHA 29 CFR 1910.134 such as training and fit testing and applicable OSHA substance specific standards.
3. The particles which can be dangerous to your health include those so small that you cannot see them.
4. Leave the contaminated area immediately and contact supervisor if dizziness, irritation, or other distress occurs.
5. Store the respirator away from contaminated areas when not in use.
6. Dispose of used product in accordance with applicable regulations.

USE LIMITATIONS:

1. Do NOT use the respirator or enter or stay in a contaminated area under the following circumstances:
 - atmosphere contains less than 19.5% oxygen.
 - atmosphere contains oil aerosols.
 - for protection against gases or vapors.
 - contaminants or their concentrations are unknown or immediately dangerous to life or health.
 - for sandblasting, paint-spray operations, asbestos.
2. Do NOT modify or misuse the respirator.
3. Do NOT use the respirator with beards or other facial hair that interferes with direct contact between the face and the edge of the respirator, or any other conditions that may prevent a good face-seal.

WARNING:

This respirator helps protect against certain contaminants. It may not eliminate the risk of contracting disease or infection. Misuse may result in sickness or death.
Materials which may come into contact with the wearer's skin could cause allergic reactions to susceptible individuals.

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THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection ¹	Respirator	Cautions and Limitations ²
		ZYB-11	
84A-7877	N95	X	ABCJMNO

1. Protection

N95-Particulate filter (95%filter efficiency level) Effective against particulate aerosols free of oil; time use restrictions may apply

2. Cautions and Limitations

- A. Not for use in atmospheres containing less than 19.5% oxygen.
- B. Not for use in atmospheres immediately dangerous to life or health.
- C. Do not exceed maximum use concentrations established by regulatory standards.
- J. Failure to properly use and maintain this product could result in injury or death.
- M. All approved respirators shall be selected, used and maintained in accordance with MSHA, OSHA and other applicable regulations.
- N. Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O. Refer to Use's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P. NIOSH does not evaluate respirators for use as surgical masks.



NIOSH N95 APPROVED



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