



El Laboratorio Nacional de Tecnología de Protección Personal (NPPTL)

Respiradores de máscara con filtro de partículas N95 aprobados por NIOSH



Actualizado el 19 de marzo de 2021

Fabricantes enumerados alfabéticamente: X, Y y Z

El respirador N95 es el más común de los siete tipos de respiradores de máscara con filtro de partículas. Este producto filtra al menos el 95% de las partículas en el aire, pero no es resistente al aceite.

Esta página web proporciona una tabla de respiradores N95 aprobados por NIOSH, enumerados alfabéticamente por fabricante. Puede seleccionar un fabricante en particular haciendo clic en la primera letra de su nombre en el índice a continuación.

Hay algunos productos que están aprobados por NIOSH como respirador N95 y también aprobados por la Administración de Alimentos y Medicamentos (FDA) como mascarilla quirúrgica. Estos productos se conocen como **respiradores quirúrgicos N95**. [Vea una definición de respiradores quirúrgicos N95](#). Para su comodidad, los respiradores quirúrgicos N95 están indicados con el **número de modelo / línea de productos en negrita seguido de (FDA)**. Si tiene un producto que cree que está aprobado por NIOSH y aprobado por la FDA que no aparece en esta lista, deberá consultar con los CDC para determinar si está aprobado por NIOSH al 1-800-CDC-INFO (1-800-232-4636) y el Centro de Dispositivos y Salud Radiológica de la FDA al 1-800-638-2041 para verificar la autorización. [Vea una tabla completa de respiradores quirúrgicos N95](#).

Descargo de responsabilidad: Los enlaces en esta sección van a sitios web fuera de CDC / NIOSH y no deben considerarse como una aprobación de su contenido o como una declaración de la política de NIOSH. El procedimiento de colocación y / o las instrucciones para el usuario, ya sea en los sitios web o en la versión PDF, no deben considerarse un respaldo oficial de su contenido ni una declaración de la política de NIOSH.

Índice: 3M A B C D E F G H I J K L M N O P Q R S T
U V W X Y Z Notas

Proveedor / fabricante e información de contacto	Número de modelo / línea de productos	Número de aprobación	Válvula Sí / No	Instrucciones para el usuario del procedimiento de colocación del fabricante
Xiantao Zhongyi Safety Protection Products Company, Ltd. 0086-728-3257535 / 3257635	ZYB-11	84A-7877	No	ZYB-11 [PDF - 97 KB]

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-21384

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Xiantao Zhongyi Safety Protection Products Co., Ltd.

Filter Type: Filter Only

Item Tested: ZYB-11

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Exhalation	Exhalation	
1	25	8.2	PASS
2	25	8.6	PASS
3	25	9.2	PASS

Overall Result: PASS

Comments:

Samples were tested on manometer 000426.

Was all equipment verified to be in calibration throughout all testing?

☒ Yes ☐ No

Signature:

Date: 26/10/2017

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-21384

Reference No.: CFR 84.182

Test: Exhalation Valve Leakage Test

STP No.: 4

Manufacturer: Xiantao Zhongyi Safety Protection Products Co., Ltd.

Item Tested: ZYB-11

LEAKAGE						
Sample	Trial #1 (mL/min.)	Trial #2 (mL/min.)	Trial #3 (mL/min.)	Average (mL/min.)	Maximum Allowable (mL/min.)	Result
Valve 1	0.00	0.00	0.00	0.00	30.00	PASS
Valve 2	0.00	0.00	0.00	0.00	30.00	PASS
Valve 3	0.00	0.00	0.00	0.00	30.00	PASS
Overall Result: PASS						

Signature:

Date: 26/10/2017

Engineering Technician

Task Number: TN-21384

Reference No.: CFR 84.182

Test: Exhalation Valve Leakage Test

STP No.: 4

Manufacturer: Xiantao Zhongyi Safety Protection Products Co., Ltd.

Item Tested: ZYB-11

Comments:

Samples were tested on Gilibrator 000041.

Was all equipment verified to be in calibration throughout all testing?

☒ Yes ☐ No

Signature:



Date: 26/10/2017

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-21384

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Xiantao Zhongyi Safety Protection Products Co., Ltd.

Item Tested: ZYB-11

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Inhalation	Inhalation	
1	35	8.4	PASS
2	35	7.9	PASS
3	35	8.4	PASS
Overall Result: PASS			

Signature:

Date: 26/10/2017

Engineering Technician

Task Number: TN-21384

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Xiantao Zhongyi Safety Protection Products Co., Ltd.

Item Tested: ZYB-11

Comments:

Samples were tested on manometer 000034.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:



Date: 26/10/2017

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-21384

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Xiantao Zhongyi Safety Protection Products Co., Ltd.

Item Tested: ZYB-11

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	10.4	5.00	0.293	0.362	PASS
2	85	10.7	5.00	0.299	0.342	PASS
3	85	11.2	5.00	0.196	0.251	PASS
4	85	10.4	5.00	0.527	0.632	PASS
5	85	11.4	5.00	0.380	0.403	PASS
6	85	11.8	5.00	1.090	1.120	PASS
7	85	11.5	5.00	1.590	1.670	PASS
8	85	11.6	5.00	0.209	0.283	PASS
9	85	10.9	5.00	0.344	0.372	PASS
10	85	10.6	5.00	0.334	0.334	PASS
11	85	10.2	5.00	0.281	0.327	PASS
12	85	10.5	5.00	0.322	0.371	PASS
13	85	10.4	5.00	0.277	0.321	PASS
14	85	11.3	5.00	0.516	0.573	PASS
15	85	10.0	5.00	0.332	0.370	PASS
16	85	11.0	5.00	0.322	0.363	PASS
17	85	10.0	5.00	0.293	0.318	PASS
18	85	10.5	5.00	0.393	0.419	PASS
19	85	10.2	5.00	0.226	0.299	PASS
20	85	10.2	5.00	0.337	0.376	PASS

Overall Result: PASS

Signature:

Date: 26/10/2017

Engineering Technician

Task Number: TN-21384

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Xiantao Zhongyi Safety Protection Products Co., Ltd.

Item Tested: ZYB-11a

Comments:

Sample 1 was tested on TSI 8130 machine 000334 using timer 000215. Samples 2-10 were tested on TSI 8130 machine 000333 using timer 000215. Samples 11-20 were tested on TSI 8130A machine 000388. Flow is measured in liters/min. Resistance is measured in mm-H₂O.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:



Date: 26/10/2017

Engineering Technician

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.

NPPTL COVID-19 Response: International Respirator Assessment

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.

CM-02 Rev.B

NPPTL COVID-19 Response: International Respirator Assessment

Xiantao Zhong Yi Safety & Protection Products Co., Ltd.
No. 101, Xianyuan Road, Xiantao City, Hubei Province, China 433000
TEL:0086-728-3257535 Fax:0086-728-3206945
www.zhongyimask.com

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

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

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



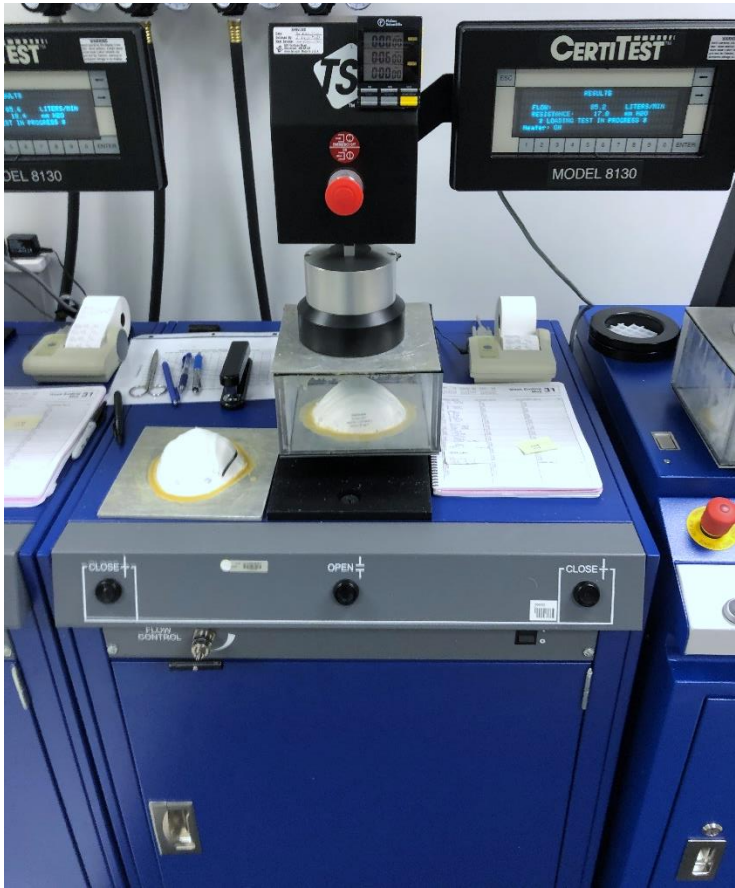
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NPPTL COVID-19 Response: International Respirator Assessment





DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-21384
Manufacturer Reference: XZSZYB-11b

Centers for Disease Control
and Prevention (CDC)

National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
626 Cochran's Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051
October 26, 2017

Marry Xu
Xiantao Zhongyi Safety Protection Products Co.,Ltd
No. 101 Xianyuan Road
Xiantao City, Hubei Province 433000
China

Dear Ms. Xu:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted January 27, 2017. This request was for approval of the model ZYB-11 air purifying filtering facepiece respirator for protections against particulates at N95 filter efficiency level. Refer to assembly matrix ZYB-11AMb.xls, revision B, dated: 12-20-2016.

This request is granted. Approval is granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired to be produced in languages other than English. Approval number TC-84A-7877 has been assigned. This respirator is approved for protection against particulates at N95 filter efficiency level.

The final respirator approval label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Jeffrey Peterson', with a long horizontal flourish extending to the right.

Jeffrey Peterson
Acting Chief, Conformity Verification and
Standards Development Branch

Enclosures

Test Data Sheet

Task Number: TN-21384

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Xiantao Zhongyi Safety Protection Products Co.,

Filter Type: Filter Only

Item Tested: ZYB-11

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Exhalation	Exhalation	
1	25	10.6	PASS
2	25	11.0	PASS
3	25	11.4	PASS

Overall Result: PASS

Comments:

Samples were tested on manometer 000283.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:

Nichole L. Petitta

Date: 3/20/2017

Engineering Technician

Test Data Sheet

Task Number: TN-21384

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Xiantao Zhongyi Safety Protection Products Co.,

Item Tested: ZYB-11

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Inhalation	Inhalation	
1	35	10.6	PASS
2	35	10.9	PASS
3	35	11.5	PASS

Overall Result: PASS

Signature:

Nichole L. Petitta

Date: 3/20/2017

Engineering Technician

Task Number: TN-21384

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Xiantao Zhongyi Safety Protection Products Co.,

Item Tested: ZYB-11

Comments:

Samples were tested on manometer 000285.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:

Nichole L. Petitta

Date: 3/20/2017

Engineering Technician

Respirator Branch

Test Data Sheet

Task Number: TN-21384

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Xiantao Zhongyi Safety Protection Products Co.,

Item Tested: ZYB-11

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	10.6	5.00	0.437	0.437	PASS
2	85	10.6	5.00	0.532	0.532	PASS
3	85	10.8	5.00	0.455	0.455	PASS
4	85	10.7	5.00	0.450	0.453	PASS
5	85	10.6	5.00	0.510	0.570	PASS
6	85	11.4	5.00	0.331	0.331	PASS
7	85	12.3	5.00	0.383	0.411	PASS
8	85	12.1	5.00	0.455	0.455	PASS
9	85	10.7	5.00	0.370	0.372	PASS
10	85	10.9	5.00	0.479	0.479	PASS
11	85	10.3	5.00	0.400	0.471	PASS
12	85	11.5	5.00	0.403	0.426	PASS
13	85	10.7	5.00	0.489	0.503	PASS
14	85	10.8	5.00	0.461	0.461	PASS
15	85	11.4	5.00	0.398	0.439	PASS
16	85	10.4	5.00	0.668	0.677	PASS
17	85	11.6	5.00	0.636	0.661	PASS
18	85	10.8	5.00	0.458	0.593	PASS
19	85	11.0	5.00	0.435	0.467	PASS
20	85	10.4	5.00	0.436	0.481	PASS

Overall Result: PASS

Signature:

Nichole L. Petitta

Date: 3/21/2017

Engineering Technician

Task Number: TN-21384

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Xiantao Zhongyi Safety Protection Products Co.,

Item Tested: ZYB-11

Comments:

Samples 1-10 were tested on TSI 8130 machine 000332 using timer 000213. Samples 11-15 were tested on TSI 8130 machine 000333. Samples 16-20 were tested on TSI 8130 machine 000334.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:

Nichole L. Petitta

Date: 3/21/2017

Engineering Technician