

NPPTL COVID-19 Response: Beyond Shelf Life/Stockpiled Respirator Assessment

Manufacturer: Handan Hengyong Protective and Clean Products Co., Ltd.

Model Tested: HY8510 (LOT # SW091208)

Date Tested: May 6, 2020

Report Prepared: May 6, 2020

These findings pertain to the Handan Hengyong Protective and Clean Products Co., Ltd., model HY8510 submitted for testing, and may not be applicable to other stockpile facilities and/or under different environmental storage conditions. All samples from the Handan Hengyong Protective and Clean Products Co., Ltd., model HY8510 (LOT # SW091208) failed the NIOSH filtration efficiency test. The maximum and minimum filter efficiency was 94.00% and 69.20%, respectively. All twenty respirators measured less than 95% efficiency. No shelf life was designated for this model by the previously held NIOSH approval holder.

NIOSH regulation sets the minimum quality and performance requirements for the approval of respirators (42 CFR 84). **NIOSH does not have requirements for shelf life or storage conditions for particulate-only APRs.** The approval holder (i.e. the entity that is granted the approval from NIOSH) is responsible for understanding how their products' design or performance may be affected by various use or storage conditions and must provide instruction for establishing the proper use, storage, and maintenance procedures for their approved products, which may include designating a shelf life. FFR or particulate filter packaging (such as the box) often includes NIOSH-approved user instructions, label information, and recommendations on shelf life. Additionally, some approval holders also disseminate recommendations related to storage and shelf life through resources such as user and web notices. The respirators tested in this study were generally not designed for long-term storage.

Based on research conducted by NIOSH and this limited testing, NIOSH does not have enough information to definitively know the level of protection that may be provided by respirators that 1) are stored for prolonged periods of times; 2) are stored under various storage conditions; or 3) have exceeded the approval holder's designated shelf life. Users of respirators that have exceeded the designated shelf life should be forewarned to avoid a false sense of confidence; these devices may not provide the same level of protection as those that have not exceeded the designated shelf life. We recommend contacting the approval holder(s) of the respirators in the stockpile with specific questions regarding the use of product beyond the manufacturer- designated shelf life.

The results provided in this letter are specific to the subset of NIOSH-approved N95s, past their designated shelf life, that were provided to NPPTL for evaluation.

These results will be added to the CDC guidance for [Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life](#).

Evaluation of Stockpiled and Beyond Manufacturer-Designated Shelf Life N95s



Test: TEB-APR-STP-0059

Manufacturer: Handan Hengyong Protective and Clean Products Co., Ltd.


Item Tested: HY8510 (LOT # SW091208)

Expiration Date: None Provided

Manufacture Date: None Provided

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	8.7	15.6	16.4	83.60
2	85	9.6	7.86	8.17	91.83
3	85	8.6	27.2	27.2	72.80
4	85	8.9	10.1	10.6	89.40
5	85	9.0	13.6	14.4	85.60
6	85	7.8	6.00	6.00	94.00
7	85	4.9	27.9	29.9	70.10
8	85	8.6	11.0	11.3	88.70
9	85	9.7	12.4	12.5	87.50
10	85	8.3	19.5	20.0	80.00
11	85	8.0	11.0	11.4	88.60
12	85	9.8	11.9	12.0	88.00
13	85	8.1	10.9	12.0	88.00
14	85	8.7	10.6	10.9	89.10
15	85	7.9	11.7	12.0	88.00
16	85	8.0	12.0	12.4	87.60
17	85	8.3	15.4	16.0	84.00
18	85	4.8	28.6	30.8	69.20
19	85	8.3	11.1	11.5	88.50
20	85	6.5	17.3	17.7	82.30
Minimum Filter Efficiency: 69.20			Maximum Filter Efficiency: 94.00		

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N95 FOLD-FLAT RESPIRATOR
Individually Hygienically Packed

- Foldable Type
- Maintenance Free
- Smooth P.P. Lining
- Clear Vision
- Adjustable Nose Piece with Inner Foam for Optimal Comfort and Fit
- FDA 510(k) Approved for Surgical Use
- Meets CDC Guidelines for TB Exposure Control
- 42CFR84 Approved Product

20 masks

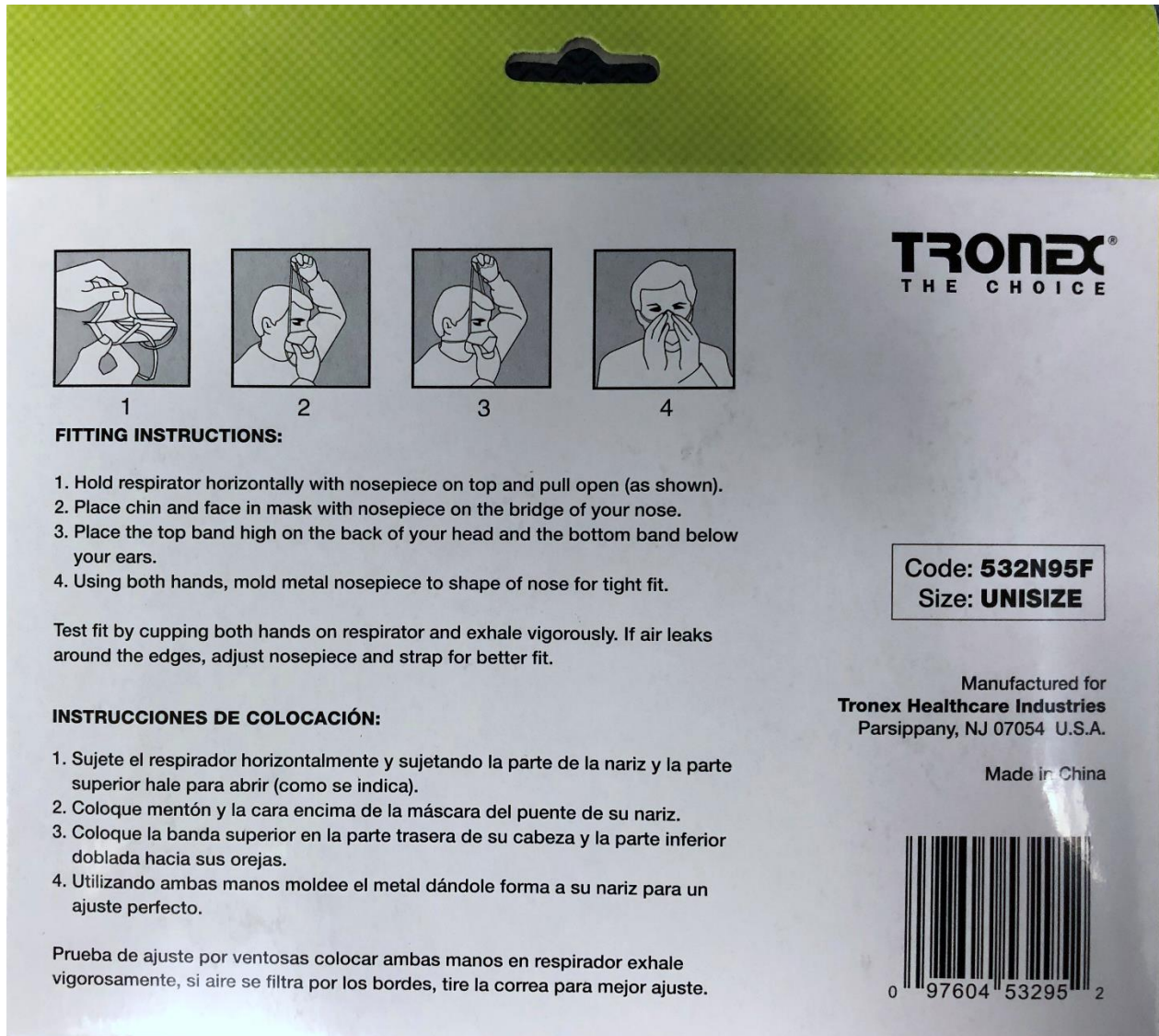
Fold Flat Style



TRONEX®
THE CHOICE

TEAR HERE

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The image shows the back of a respirator package. At the top is a green textured strip with a black hanging tab. Below this is a white area containing four numbered illustrations (1-4) showing the steps to put on the respirator. To the right of these illustrations is the Tronex logo with the tagline 'THE CHOICE'. Below the illustrations are the fitting instructions in English. To the right of the English instructions is a box containing the code '532N95F' and the size 'UNISIZE'. Below the English instructions are the fitting instructions in Spanish. To the right of the Spanish instructions is the manufacturer information: 'Manufactured for Tronex Healthcare Industries, Parsippany, NJ 07054 U.S.A.' and 'Made in China'. At the bottom right is a barcode with the numbers '0 97604 53295 2' below it.

TRONEX®
THE CHOICE

FITTING INSTRUCTIONS:

1. Hold respirator horizontally with nosepiece on top and pull open (as shown).
2. Place chin and face in mask with nosepiece on the bridge of your nose.
3. Place the top band high on the back of your head and the bottom band below your ears.
4. Using both hands, mold metal nosepiece to shape of nose for tight fit.

Test fit by cupping both hands on respirator and exhale vigorously. If air leaks around the edges, adjust nosepiece and strap for better fit.

INSTRUCCIONES DE COLOCACIÓN:

1. Sujete el respirador horizontalmente y sujetando la parte de la nariz y la parte superior hale para abrir (como se indica).
2. Coloque mentón y la cara encima de la máscara del puente de su nariz.
3. Coloque la banda superior en la parte trasera de su cabeza y la parte inferior doblada hacia sus orejas.
4. Utilizando ambas manos moldee el metal dándole forma a su nariz para un ajuste perfecto.

Prueba de ajuste por ventosas colocar ambas manos en respirador exhale vigorosamente, si aire se filtra por los bordes, tire la correa para mejor ajuste.


Code: **532N95F**
Size: **UNISIZE**

Manufactured for
Tronex Healthcare Industries
Parsippany, NJ 07054 U.S.A.


Made in China

0 97604 53295 2

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Handan Heng Yong Protective and Clean Products Company, Ltd.
 1-1 1201, 455 Gongnong Rd.
 Shijiazhuang, Hebei, P. R. China
 Tel: 0311-87260765



THESE RESPIRATORS ARE APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS			
TC-	PROTECTION ¹	HY 8510 TYPE N95 RESPIRATOR	CAUTIONS AND LIMITATIONS ²
84A-4276	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 percent oxygen.
- B. Not 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, fitted, 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 User'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.

WARNING:

1. This product does not eliminate the risk of contracting any disease or infection.
2. Failure to follow all instructions and limitations on the use of this product could reduce the effectiveness of respirator and result in sickness or death.
3. A properly selected respirator is essential to protect your health. Before using this respirator, consult an Industrial Hygienist or Occupational Safety Professional to determine the suitability for your intended use.
4. This product does not supply oxygen. Use only in adequately ventilated areas containing sufficient oxygen to support life. Do not use this respirator when oxygen concentration is less than 19.5%.
5. Do not use when concentrations of contaminants are immediately dangerous to health or life.
6. Leave work area immediately and return to fresh air if (a) breathing becomes difficult, or (b) dizziness or other distress occurs.
7. Facial hairs or beards and certain facial characteristics may reduce the effectiveness of this respirator.
8. Never alter or modify this respirator in any way.
9. Only for single use. No maintenance necessary. Discard the used respirator after single use.
10. Keep respirators in the display box away from direct sunlight until use.

ADVERTENCIAS:

1. Este producto no elimina el riesgo de contraer una enfermedad o infección.
2. Si no se siguen cuidadosamente todas la indicaciones y advertencias al utilizar el respirador, la efectividad del mismo disminuirá y podrá resultar en enfermedad o muerte.
3. La elección de un respirador adecuado es esencial para proteger su salud. Antes de usar este respirador, consulte un experto en Higiene Industrial o Profesional de Seguridad Ocupacional para determinar si su uso previsto es adecuado.
4. Este respirador no aporta oxígeno. Solamente usar en áreas adecuadamente ventiladas con oxígeno suficiente para soportar la vida. No usar este respirador cuando la concentración de oxígeno es inferior al 19.5%.
5. No usar cuando las concentraciones de contaminantes seas peligrosas a la salud o vida.
6. Abandone el área de trabajo inmediatamente y vuelva al área con aire fresco. Si (a) la respiración se hace dificultosa o (b) siente vértigo, mareos y otro malestar.
7. Barbas y ciertas características faciales pueden reducir la eficacia de este respirador.
8. Nunca modifique o altere el respirador.
9. Solo para uso único, no requiere mantenimiento, deshacerse del respirador usado después de su utilización.
10. Mantenga los respiradores nuevos en su casa lejos de la luz del sol antes del uso.



Code: 532N95F
Size: UNISIZE

Lot No. SW091208

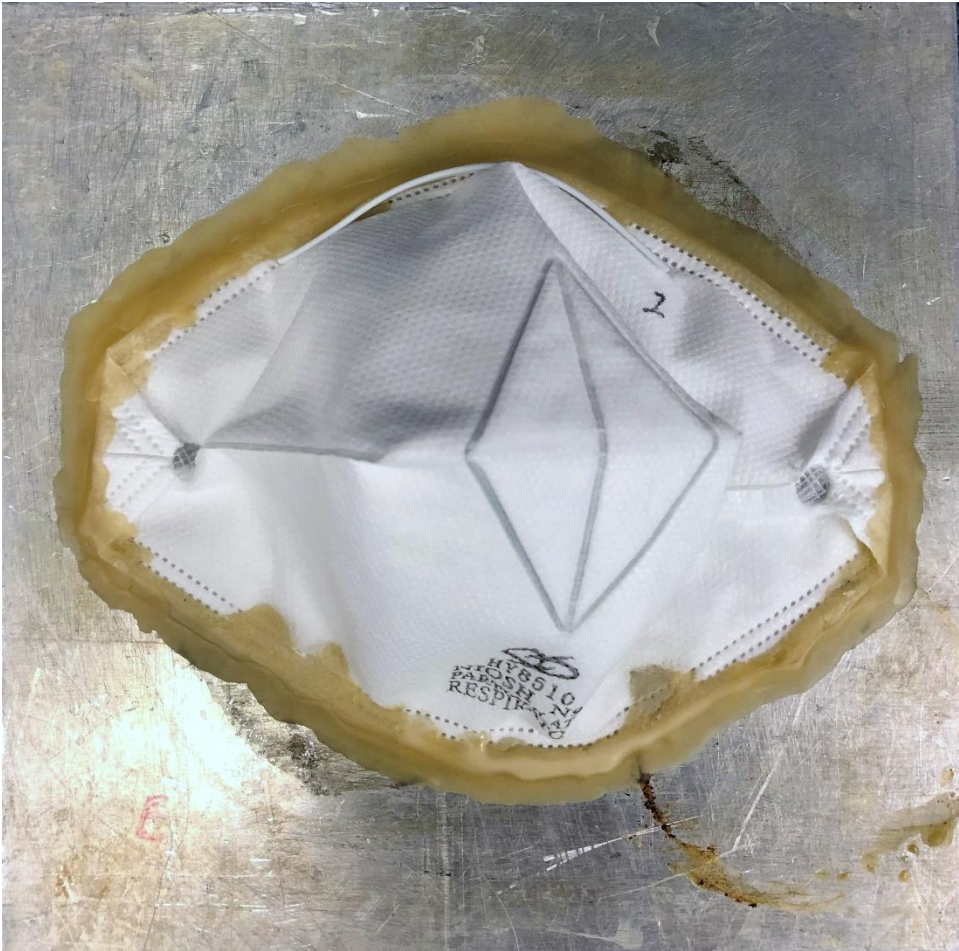




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