NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shanghai Dasheng Health Products Manufacture Co., Ltd.
Model Tested: DTC3X
Date Tested: November 19, 2020

These findings pertain to the Shanghai Dasheng Health Products Manufacture Co., Ltd., model DTC3X. The packaging and labeling for this product indicate that it is a NIOSH-approved product, under approval number TC-84A-4329. The packaging also indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Thirty respirators were submitted for evaluation. The respirators were sampled into groups of ten 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.

The maximum and minimum filter efficiency was 99.90% and 21.30%, respectively. Nineteen respirators measured more than 95%. Eleven respirators measured less 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).
NPPTL COVID-19 Response: International Respirator Assessment

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059
Date Tested: November 19, 2020
Report Prepared: November 20, 2020
Manufacturer: Shanghai Dasheng Health Products Manufacture Co., Ltd.
Item Tested: DTC3X (Sample Group 1 of 3)
Country of Certification: China (GB2626-2006), USA (claimed, 42 CFR 84)

<table>
<thead>
<tr>
<th>Filter</th>
<th>Flow Rate (Lpm)</th>
<th>Initial Filter Resistance (mmH2O)</th>
<th>Initial Percent Leakage (%)</th>
<th>Maximum Percent Leakage (%)</th>
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Minimum Filter Efficiency: 92.06 Maximum Filter Efficiency: 99.90

- 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.
NPPTL COVID-19 Response: International Respirator Assessment

Evaluation of International Respirators

**Test:** Modified TEB-APR-STP-0059

**Date Tested:** November 19, 2020

**Report Prepared:** November 20, 2020

**Manufacturer:** Shanghai Dasheng Health Products Manufacture Co., Ltd.

**Item Tested:** DTC3X (Sample Group 2 of 3)

**Country of Certification:** China (GB2626-2006), USA (claimed, 42 CFR 84)

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Minimum Filter Efficiency: 27.80  
Maximum Filter Efficiency: 99.86

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NPPTL COVID-19 Response: International Respirator Assessment

Evaluation of International Respirators

**Test:** Modified TEB-APR-STP-0059

**Date Tested:** November 19, 2020

**Report Prepared:** November 20, 2020

**Manufacturer:** Shanghai Dasheng Health Products Manufacture Co., Ltd.

**Item Tested:** DTC3X (Sample Group 3 of 3)

**Country of Certification:** China (GB2626-2006), USA (claimed, 42 CFR 84)

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</table>

- Minimum Filter Efficiency: 21.30
- Maximum Filter Efficiency: 99.88

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<table>
<thead>
<tr>
<th>TC-</th>
<th>Protection</th>
<th>Respirator</th>
<th>Cautions and Limitations</th>
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<td>X</td>
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</table>

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.
   D. Failure to properly use and maintain this product could result in injury or death.
   E. All approved respirators shall be selected, tested, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
   F. Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
   G. Refer to User Instructions and/or maintenance manuals for inflammation on use and maintenance of these respirators.
   H. NIOSH does not evaluate respirators for use as surgical masks.

**WARNING:**

**NIOSH APPROVED: N95**

95% efficient against particulate aerosols free of oil. This respirator helps protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting disease or infection. Missuse may result in sickness or death.
1. Prestretch top and bottom straps before placing respirator on the face.
2. Cup the respirator in your hand, with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand.
3. Position the respirator under your chin with the nosepiece up. Pull the top strap over your head resting it high at the top back of your head. Pull the bottom strap over your head and position it around the neck below the ears.
4. Place your fingertips from both hands at the top of the metal nosepiece. Using two hands mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece. Pinching the nosepiece using one hand may result in improper fit and less effective respirator performance. Use two hands.
5. Perform a User 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 four. If air leaks at the respirator edges, work the straps back along the side of head. If you CANNOT achieve a proper fit, DO NOT enter the contaminate area. See your supervisor.

Removal Instructions:
See step 3 of Fitting Instructions and cup respirator in hand to maintain position on face. Pull bottom strap overhead. Still holding respirator in position. Pull top strap overhead and remove respirator.

This respirator contains no components made from natural rubber latex.

NIOSH Approved: N95
At least 95% filtration efficiency against solid and liquid aerosols that do not contain oil.

PROTECTION:
N95-Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply.

CAUTIONS AND LIMITATION:
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.
D. Failure to properly use and maintain this product could result in injury or death.
E. All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
F. Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
G. Refer to User instructions and/or maintenance manuals for information on use and maintenance of these respirators.
H. NIOSH does not evaluate respirations for use as surgical masks.
NPPTL COVID-19 Response: International Respirator Assessment

N95 Particulate Respirator

WARNING:
This respirator helps protect against certain particles. Misuse may result in sickness or death. For proper use, see supervisor.

IMPORTANT:
Before use, the wearer must read and understand these User Instructions. Keep insert for reference.

Use For:
Solids such as those from processing minerals, coal, iron ore, flour, and certain other substances. Liquid or non-oil based particles from sprays that do not also emit oil aerosols or vapors.

Do Not Use For:
Paint spray, oil aerosols, gases, vapors, asbestos or sandblasting. This respirator does not supply oxygen.

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. In Canada, CSA standard Z94.4-93 requirements must be met.
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. This respirator does not supply oxygen. Do not use in atmospheres containing less than 19.5% oxygen.
2. Do not use when concentrations of contaminants are immediately dangerous to life and health are unknown or when concentrations exceed 10 times the permissible exposure limit (PEL) or according to specific OSHA standards or applicable government regulations, whichever is lower.
3. Do not alter, abuse or misuse this respirator.
4. Do not use with beards or other facial hair or other conditions that prevent a good seal between the face and the edge of the respirator.

Time Use Limitations:
If respirator becomes damaged, soiled, or breathing becomes difficult, leave the contaminated area and replace the respirator.

Fitting Instructions:
To be followed each time respirator is worn.
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