

## NPPTL COVID-19 Response: International Respirator Assessment

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

Model Tested: DTC3X

Date Tested: July 24 & 27, 2020

These findings pertain to the Shanghai Dasheng Health Products Manufacture Co., Ltd., model DTC3X. The packaging and labeling indicate that it is a NIOSH-approved product, under approval number TC-84A-4329. Shanghai Dasheng Health Products Manufacture Co., Ltd., through correspondence with NIOSH, has indicated that their products have been counterfeited.

Sixty respirators were submitted for evaluation. Thirty respirators were sampled into groups of ten for evaluation using the modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found [here](#). Due to special circumstances with this submission, additional testing was performed. Twenty respirators were evaluated using the full version of NIOSH STP TEB-APR-STP-0059 and three respirators were evaluated for exhalation and inhalation resistance using STP TEB-APR-STP-0003 and TEB-APR-STP-0007, respectively. Seven respirators were not evaluated.

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 99.83% and 99.29%, respectively. All fifty respirators, that were evaluated for filter efficiency, measured more than 95%. Exhalation and Inhalation resistance values were within the maximum allowable tolerance.

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.

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 respirators 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:** July 24, 2020

**Report Prepared:** July 29, 2020

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

**Item Tested:** DTC3X (Sample Group 1 of 3)

**Country of Certification:** USA (claimed, 42 CFR 84)

Pictures have been added to the end of this report.

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	10.9	0.34	0.43	99.57
2	85	10.6	0.34	0.45	99.55
3	85	10.8	0.28	0.35	99.65
4	85	12.1	0.39	0.50	99.50
5	85	13.9	0.40	0.40	99.60
6	85	12.0	0.49	0.55	99.45
7	85	10.9	0.39	0.52	99.48
8	85	13.0	0.33	0.35	99.65
9	85	11.7	0.48	0.52	99.48
10	85	13.8	0.40	0.41	99.59
<b>Minimum Filter Efficiency: 99.45</b>			<b>Maximum Filter Efficiency: 99.65</b>		

- 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.

**Evaluation of International Respirators**

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

**Date Tested:** July 24, 2020

**Report Prepared:** July 29, 2020

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

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

**Country of Certification:** USA (claimed, 42 CFR 84)

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
11	85	14.2	0.36	0.36	99.64
12	85	13.6	0.29	0.29	99.71
13	85	14.1	0.35	0.35	99.65
14	85	12.3	0.60	0.67	99.33
15	85	13.2	0.23	0.23	99.77
16	85	12.3	0.39	0.48	99.52
17	85	11.6	0.60	0.71	99.29
18	85	11.2	0.56	0.68	99.32
19	85	12.2	0.45	0.56	99.44
20	85	12.5	0.57	0.67	99.33
<b>Minimum Filter Efficiency: 99.29</b>			<b>Maximum Filter Efficiency: 99.77</b>		

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## Evaluation of International Respirators

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

**Date Tested:** July 24, 2020

**Report Prepared:** July 29, 2020

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

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

**Country of Certification:** USA (claimed, 42 CFR 84)

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
21	85	15.8	0.31	0.31	99.69
22	85	18.8	0.49	0.49	99.51
23	85	17.2	0.51	0.51	99.49
24	85	10.5	0.44	0.44	99.56
25	85	12.5	0.51	0.51	99.49
26	85	16.0	0.40	0.40	99.60
27	85	13.4	0.26	0.26	99.74
28	85	17.6	0.33	0.33	99.67
29	85	19.7	0.37	0.37	99.63
30	85	15.9	0.29	0.29	99.71
<b>Minimum Filter Efficiency: 99.49</b>			<b>Maximum Filter Efficiency: 99.74</b>		

- 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.
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**Evaluation of International Respirators**

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

**Date Tested:** July 27, 2020

**Report Prepared:** July 29, 2020

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

**Item Tested:** DTC3X

**Country of Certification:** USA (claimed, 42 CFR 84)

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
31	85	13.7	0.22	0.22	99.78
32	85	12.2	0.28	0.28	99.72
33	85	13.6	0.17	0.17	99.83
34	85	12.1	0.37	0.37	99.63
35	85	11.3	0.45	0.45	99.55
36	85	11.6	0.50	0.50	99.50
37	85	14.4	0.22	0.22	99.78
38	85	11.2	0.53	0.53	99.47
39	85	12.2	0.46	0.46	99.54
40	85	11.5	0.60	0.60	99.40
41	85	11.7	0.49	0.49	99.51
42	85	15.5	0.19	0.19	99.81
43	85	11.5	0.53	0.53	99.47
44	85	15.9	0.30	0.30	99.70
45	85	16.0	0.24	0.24	99.76
46	85	17.0	0.28	0.28	99.72
47	85	11.9	0.53	0.53	99.47
48	85	15.0	0.22	0.22	99.78
49	85	11.5	0.48	0.48	99.52
50	85	15.3	0.25	0.25	99.75
<b>Minimum Filter Efficiency: 99.40</b>			<b>Maximum Filter Efficiency: 99.83</b>		

## Evaluation of International Respirators

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**Test:** TEB-APR-STP-0003 and TEB-APR-STP-0007

**Date Tested:** July 27, 2020

**Report Prepared:** July 29, 2020

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

**Item Tested:** DTC3X

**Country of Certification:** USA (claimed, 42 CFR 84)

<b>Filter</b>	<b>Maximum Allowable Exhalation Resistance (mm of H<sub>2</sub>O)</b>	<b>Actual Exhalation Resistance (mm of H<sub>2</sub>O)</b>	<b>Maximum Allowable Inhalation Resistance (mm of H<sub>2</sub>O)</b>	<b>Actual Inhalation Resistance (mm of H<sub>2</sub>O)</b>
<b>51</b>	20	10.7	35	11.4
<b>52</b>	20	10.9	35	11.9
<b>53</b>	20	10.4	35	11.9





## 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.





# NPPTL COVID-19 Response: International Respirator Assessment



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**THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION :**

TC -	Protection <sup>1</sup>	Respirator	Cautions and Limitations <sup>2</sup>
		<b>DTC3X</b>	
<b>84A-4329</b>	<b>N95</b>	<b>X</b>	<b>ABCJMNOP</b>

## 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, 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 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:**

### 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 contacting disease or infection. Misuse may result in sickness or death.



### Fitting Instructions:

to be followed each time respirator is worn.



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 with 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 sides of your head. If you CANNOT achieve a proper fit, DO NOT enter the contaminated 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 over head 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.**



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