

NPPTL COVID-19 Response: International Respirator Assessment

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

Model Tested: DTC3X

Date Tested: May 11, 2020

These findings pertain to products labeled as Shanghai Dasheng Health Products Manufacture Co., Ltd., model DTC3X. The labeling for this product indicates 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.

Forty 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 98.34% and 90.45%, respectively. Thirty three respirators measured more than 95%. Seven 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 \(during known shortages\)](#).

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: May 11, 2020

Report Prepared: May 11, 2020

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

Item Tested: DTC3X (Sample Group 1 of 4)

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 ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	12.8	1.99	1.99	98.01
2	85	11.9	2.19	2.19	97.81
3	85	11.4	1.67	1.67	98.33
4	85	11.7	2.51	2.51	97.49
5	85	10.7	3.69	3.69	96.31
6	85	9.1	7.09	7.30	92.70
7	85	10.8	2.00	2.00	98.00
8	85	8.2	8.76	9.55	90.45
9	85	11.5	2.24	2.24	97.76
10	85	11.6	1.72	1.72	98.28
Minimum Filter Efficiency: 90.45			Maximum Filter Efficiency: 98.33		

- 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.

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Test: Modified TEB-APR-STP-0059

Date Tested: May 11, 2020

Report Prepared: May 11, 2020

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

Item Tested: DTC3X (Sample Group 2 of 4)

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

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
11	85	11.4	2.25	2.25	97.75
12	85	9.3	5.14	5.14	94.86
13	85	9.8	2.89	2.89	97.11
14	85	11.4	2.22	2.22	97.78
15	85	11.8	1.97	1.97	98.03
16	85	11.4	2.15	2.15	97.85
17	85	10.9	4.01	4.01	95.99
18	85	10.6	2.89	2.89	97.11
19	85	9.6	4.89	4.89	95.11
20	85	11.4	2.64	2.64	97.36
Minimum Filter Efficiency: 94.86			Maximum Filter Efficiency: 98.03		

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Test: Modified TEB-APR-STP-0059

Date Tested: May 11, 2020

Report Prepared: May 11, 2020

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

Item Tested: DTC3X (Sample Group 3 of 4)

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

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
21	85	13.0	1.71	1.71	98.29
22	85	11.4	1.93	1.93	98.07
23	85	11.3	1.89	1.89	98.11
24	85	11.4	2.39	2.39	97.61
25	85	9.1	5.09	5.22	94.78
26	85	8.7	6.18	6.16	93.84
27	85	12.2	2.78	2.78	97.22
28	85	10.3	4.28	4.28	95.72
29	85	11.1	1.88	1.88	98.12
30	85	11.2	1.78	1.78	98.22
Minimum Filter Efficiency: 93.84			Maximum Filter Efficiency: 98.29		

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Test: Modified TEB-APR-STP-0059

Date Tested: May 11, 2020

Report Prepared: May 11, 2020

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

Item Tested: DTC3X (Sample Group 4 of 4)

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

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
31	85	9.8	3.84	3.84	96.16
32	85	9.4	5.25	5.25	94.75
33	85	11.8	4.34	4.34	95.66
34	85	11.9	2.22	2.22	97.78
35	85	10.3	2.65	2.65	97.35
36	85	9.0	7.11	7.35	92.65
37	85	10.2	3.20	3.20	96.80
38	85	11.8	1.72	1.72	98.28
39	85	8.8	6.75	6.91	93.09
40	85	11.3	1.66	1.66	98.34
Minimum Filter Efficiency: 92.65			Maximum Filter Efficiency: 98.34		

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Shanghai Dasheng Health Products Manufacture Co, Ltd
 No 228 Shihui Road, Songjiang, Shanghai 201613, China
 TEL+86-21-5783126 Fax+86-21-57784148



THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection1	Respirator	Cautions and Limitations
		DTC3X	
84A-4329	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, tested, 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 respirator.
- 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.



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