### NPPTL COVID-19 Response: International Respirator Assessment

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

Model Tested: DTC3X Date Tested: June 5, 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 meets EN149:2001+A1:2009 (the European standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking).

Ten respirators were submitted 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.

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 100.00% and 99.27%, respectively. All ten respirators measured more than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, 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.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. 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 <u>Crisis Capacity Strategies (during known</u> shortages).

## **Evaluation of International Respirators**



Pictures have been added to the

end of this report.

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

Date Tested: June 5, 2020

Report Prepared: June 5, 2020

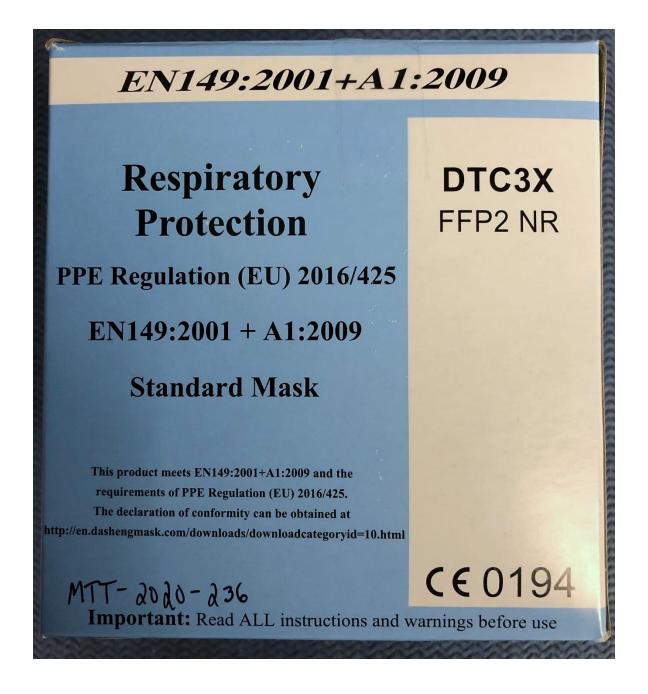
Manufacturer: Shanghai Dasheng Health Products Manufacture Co., Ltd.

Item Tested: DTC3X

Country of Certification: China (EN149:2001+A1:2009)

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	17.9	0.08	0.08	99.92
2	85	20.8	0.00	0.00	100.00
3	85	18.2	0.04	0.04	99.96
4	85	20.4	0.73	0.73	99.27
5	85	24.9	0.13	0.13	99.87
6	85	19.3	0.08	0.08	99.92
7	85	21.2	0.07	0.07	99.93
8	85	19.0	0.3	0.03	99.97
9	85	22.8	0.24	0.24	99.76
10	85	18.1	0.05	0.05	99.95
Minimum Filter Efficiency: 99.27 Maximum Filter Efficiency: 100.00					

- 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.



## FILTERING FACE MASK

## Warning

### PLEASE READ THESE INSTRUCTIONS FULLY BEFORE USING THIS PRODUCT

- Failure to follow all instructions and limitations on the use of this product, or failure to achieve proper fit, may result in damage to your health or death.
- A properly selected respirator is essential to protect your health. Before using this respirator consult a suitably qualified safety
  professional to determine the suitability of the product for your intended use.
- This product does not supply oxygen. Use only in adequately ventilated areas containing sufficient oxygen to support life. Do
  not use this respirator when the oxygen concentration is less than 19.5%.
- 4. Do not use when concentrations of contaminants are immediately dangerous to health or life. Do not use this product in an explosive atmosphere.
- 5. Leave the work area immediately if:
  - a) breathing becomes difficult or b) dizziness or other distress occurs.
- 6. Facial hair, beards and certain facial characteristics may reduce the effectiveness of this respirator.
- 7. Never alter or modify this respirator in any way (except as indicated in the instructions).
- 8. "NR" means this particle filtering half mask shall not be used for more than one shift. No maintenance is necessary. Discard respirator after use or if damaged in any way.
- The length of time this respirator can be used depends on contaminants present but should not exceed one shift. The respirator should be replaced sooner if breathing becomes difficult.
- 10. The head straps are made of synthetic rubber, which may cause skin allergies. Remove the mask immediately if irritation occurs
- 11. Keep respirators in the display box away from direct sunlight or contaminants until use. Ambient storage conditions as temperature between -30oC to +70oC, and relative humidity <80%.
- 12. Unless this is fitted according to the "Easy to use" instructions the respirator will not provide the expected level of protection.
- 13. This respirator is suitable for use in protection against the non-toxic solid and liquid aerosols.
- 14. Failure to achieve proper fit may result in serious health damage or death.
- 15. See information supplied by the manufacturer.
- 16. The respirators must be stored and transported in their original package and protected by the storage temperature and humidity as suggested by the manufacturer.

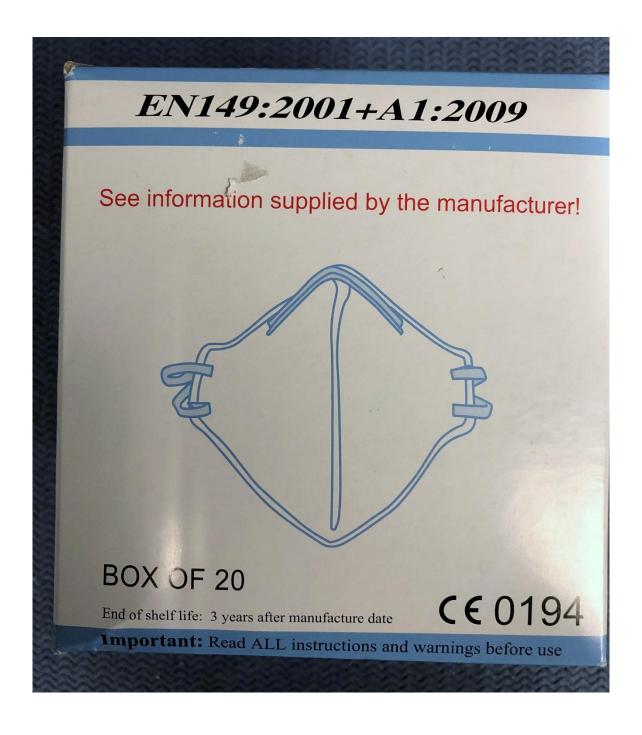
Notified Body: 0194

INSPEC International Limited

56 Leslie Hough Way, Salford, Greater Manchester, M6 6AJ, UK

**C**€ 0194

Important: Read ALL instructions and warnings before use



# FILTERING FACE MASK

# Easy to Use:



1. Hold the mask in hand with the nosepiece up. Allow headband to hang freely.



2. Position the mask under the chin covering mouth and nose.



3. Pull the headband over the head and position



4. Press soft nosepiece to conform snugly around the nose.



 To check fit, cup both hands over the mask and exhale vigorously. If air flows around nose, tighten the nosepiece. If air leaks around the edge, reposition the headband for better fit. Re-check the seal and repeat the procedure until the mask is sealed properly.

### Manufacturer:

Shanghai Dasheng Health Products Manufacture Co., Ltd. No. 228 Shihui Road, Songjiang, Shanghai, P.R.China

## **Usage & Limitations:**

This respirator is suitable for use in protection against the non-toxic solid and liquid aerosols.

Do not use out of the scope of use defined in the warnings. Failure to properly use this product may result in serious health damage or death.

FFP1 NR: Filter Efficiency 80%; Allocated Protection Factor (FPA) is 4; Examples of applications are Handling of stone / rubble / cellulose.

FFP2 NR: Filter Efficiency 94%; Allocated Protection Factor (FPA) is 10, Examples of applications are Sanding of soft wood, composite materials, rust, putty, plaster, plastics / cutting, deburring, grinding, drilling of metal.

FFP3 NR: Filter Efficiency 99%; Allocated Protection Factor (FPA) is 20; Examples of applications are Sanding of hard wood (beech, oak) / treatment of wood using copper, chrome or arsenic based products / impact stripping of paint / sanding of cement

#### Check before use:

The mask must be selected properly for intended application.

An individual risk assessment must be evaluated. Check the mask that it is undamaged with no visible defects. Check that the expiry date has not been reached (see the packaging).

Check the protection class (FFP1 NR/ FFP2 NR/ FFP3 NR) is appropriate for the product used and its concentration.

Do not use the mask if a defect is present or the expiry date has been exceeded.

**C€** 0194

Important: Read ALL instructions and warnings before use











