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 Crisis Capacity Strategies (during known shortages).
Evaluation of International Respirators

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


<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>
<th>Filter Efficiency</th>
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<tbody>
<tr>
<td>1</td>
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<td>18.1</td>
<td>0.05</td>
<td>0.05</td>
<td>99.95</td>
</tr>
</tbody>
</table>

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.

Respiratory Protection

PPE Regulation (EU) 2016/425


Standard Mask


MTT- 2020 - 236

Important: Read ALL instructions and warnings before use
See information supplied by the manufacturer!

End of shelf life: 3 years after manufacture date

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 behind head.
4. Press soft nosepiece to conform snugly around the nose.
5. 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.

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 (FPF) is 4; Examples of applications are Handling of stone/rubble/cellulose.

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

FFP3 NR: Filter Efficiency 99%; Allocated Protection Factor (FPF) 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.

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

Important: Read ALL instructions and warnings before use

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