NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Oco Healthcare Co., Ltd.
Model Tested: Clapiel Health Yellow Dust Prevention Mask 36° (KF94)
Date Tested: November 9, 2020

These findings pertain to the Oco Healthcare Co., Ltd., Clapiel Health Yellow Dust Prevention Mask 36° (KF94). The KF94 on the packaging for this product implies that these respirators were made in Korea. However, there is no indication that the product meets the requirements of KMOEL-2017-64 (the Korean standard).

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 98.91% and 98.02%, 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 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).
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Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: November 9, 2020

Report Prepared: November 10, 2020

Manufacturer: Oco Healthcare Co., Ltd.

Item Tested: Clapiel Health Yellow Dust Prevention Mask 36° (KF94)

Country of Certification: UNKNOWN

<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>
<td>85</td>
<td>10.0</td>
<td>1.61</td>
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<td>98.39</td>
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<td>10.0</td>
<td>1.61</td>
<td>1.61</td>
<td>98.39</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 98.02
Maximum Filter Efficiency: 98.91

- 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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HOW TO USE
1. Untold the mask. 2. Cover the toiled middle of the mask to the nose. 3. Place both straps on the ear to secure their position. 4. Adjust the nose bridge to properly fit the face.

CAUTIONS
1. Do not cover the nose with a towel or tissue and wear the mask on top of it. 2. Do not use in closed area with an oxygen content of less than 18%. 3. Do not crush or deform the mask. 4. Do not use the mask if it is contaminated inside. 5. Do not wash the mask. 6. In case the mask is uncomfortable to wear, such as pregnant women, respiratory patients, cardiovascular patients, children, and the elderly, please stop using and consult a doctor or specialist if necessary.

MATERIALS
Surface(Non-woven Fabric), Filter(Non-woven Fabric), Linina(Non-woven Fabric), Supporting Body(Non-Woven Fabric), Nose Bridge(Polyethylene Sheath Wire), Strap(Polyurethane nylon strap)

HOW TO STORAGE
Store at room temperature in sealed container (11℃~30℃)

MADE IN KOREA
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HOW TO USE
1. Unfold the mask, 2. Cover the folded middle of the mask to the nose, 3. Place both straps on the ear to secure their position, 4. Adjust the nose bridge to perfectly fit the face.

CAUTIONS
1. Do not cover the nose with a towel or tissue and wear the mask on top of it.
2. Do not use in closed area with an oxygen content of less than 18%.
3. Do not crush or deform the mask. 4. Do not use the mask if it is contaminated inside.
5. Do not wash the mask.
6. In case the mask is uncomfortable to wear, such as pregnant women, respiratory patients, cardiovascular patients, children, and the elderly, please stop using and consult a doctor or specialist if necessary.

MATERIALS
Surface (Non-woven Fabric), Filter (Non-woven Fabric), Lining (Non-woven Fabric), Supporting Body (Non-woven Fabric), Noise Bridges (Polyethylene Sheath Wire), Strap (Polyurethane nylon strap).

HOW TO STORAGE
Store at room temperature in sealed container (11°C~30°C).

MADE IN KOREA

1005003 EXP23.07.02
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[Images of respirator masks]

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