NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Dongguan Leihuo Medical Device Co., Ltd.
Model Tested: KN95 MASK/CREATIVE GUARD
Date Tested: May 26, 2021

These findings pertain to the Dongguan Leihuo Medical Device Co., Ltd., model KN95 MASK/CREATIVE GUARD. The packaging for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Thirty respirators were submitted for evaluation. The samples were tested using the 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 96.06% and 64.36%, respectively. Nine respirators measured more than 95% filter efficiency. Twenty-one respirators measured less than 95% filter efficiency.

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)](#).
**Test:** Modified TEB-APR-STP-0059

**Date Tested:** May 26, 2021

**Report Prepared:** May 26, 2021

**Manufacturer:** Dongguan Leihuo Medical Device Co., Ltd.

**Item Tested:** KN95 MASK/CREATIVE GUARD

**Country of Certification:** China (GB2626-2006)

<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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**Minimum Filter Efficiency:** 70.62%  **Maximum Filter Efficiency:** 95.99%

- 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.
NPPTL COVID-19 Response: International Respirator Assessment

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

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</table>

Minimum Filter Efficiency: 64.36%  Maximum Filter Efficiency: 95.77%

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**Minimum Filter Efficiency:** 64.71%  **Maximum Filter Efficiency:** 96.06%

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KN95 MASK

Protective Face Mask

- 5-ply Premium Quality Mask
- 3D Breathable Structure
- Filtration Efficiency ≥ 95%
- Suitable for Protection of PM2.5 haze particles, chemicals, dust, air pollution, pollen, food, coal dust, cement dust, and processing manufacturing

PRODUCT STANDARD: GB2626-2006
DISPOSABLE
NPPTL COVID-19 Response: International Respirator Assessment

PRODUCT INFORMATION

Product Name: KN95 MASK/CREATIVE GUARD
Main Materials: Non-woven fabric, melt-blown filtering, needle punched cotton with protective five-layer material, adjustable nose clip, & elastic ear-loop strings
Product Standard: GB2626-2006
Expiration Date: 3 years from Date of Manufacture on product packaging
Note: Before using, check to make sure product is intact
Storage Conditions: It should be stored in a dry, ventilated, non-corrosive gas environment, away from fire sources and flammable materials
Disposable Product: This is a disposable product and should be disposed after use

PRECAUTIONS

- It is limited to respiratory protection only against non-oily particles
- Do not use in an environment above 50° C
- Do not use in an environment with an oxygen content of less than 20%
- Do not use in toxic gas environment
- Do not wear mask if unventilated, hard to breath, or during sleep
- Not recommended for children
- This is a disposable product and should be disposed after use
- In case of any discomfort or adverse reactions during use, discontinue use immediately

Date of Manufacture: April 2020
Lot No.: 42001-10012422
MFG. Date: April 2020
Packaging: Respiratory Face Mask
Made in China

Creative Guard® is a trademark of Creative Products, Inc.
Creative Products, Inc.
2710 East 60th Street
Van Nuys, CA 91405
Creative Products, Inc. Operator No: 10884333
NPPTL COVID-19 Response: International Respirator Assessment

RANGE OF APPLICATION

• Suitable for Protection of PM2.5 haze particles, chemicals, dust, air pollution, pollen, food, coal dust, cement dust, and processing manufacturing

• Filtration Efficiency ≥ 95%

INSTRUCTIONS FOR USE

Instructions for Use

1. Open the mask & make sure the top of the mask is facing up

2. Cover mouth and nose with the mask and adjust to fit face

3. Extend the ear loop strings to lock-in mask around ears

4. Press adjustable nose bridge around nose for secure fit
NPPTL COVID-19 Response: International Respirator Assessment
Product Name: KN95 MASK/CREATIVE GUARD

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- Do not wear a mask if unventilated, hard to breathe, or during sleep
- Not recommended for children
- This is a disposable product and should be disposed after use
- In case of any discomfort or adverse reactions during use, discontinue use immediately

Instructions for Use:

1. Place mask & make sure the color side is facing up
2. Cover mouth and nose with the mask and adjust to fit face
3. Place one ear-loop attaching strap around ear
4. Place adjustable nose bridge around nose for secure fit

Date of Manufacture: April 2020
Lot No.: A2001
MFG. Operator No.: 10063202
Device Listing No.: D375637
Manufacture: Dongguan Leihuo Medical Device Co., LTD
Dongshan Yongshenglu No.47 Room 101, Dongguan, Guangdong, 523800, China
Proprietary Name: KN95 MASK
Manufactured for: "Creative Guard" is a trademark of Creative Products, Inc.
Creative Products, Inc.
2320 East 49th Street
Vernon, CA 90058
Creative Products Inc. Operator No.: 1006833

Made in China
NPPTL COVID-19 Response: International Respirator Assessment