

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 \(during known shortages\)](#).

Evaluation of International Respirators

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)

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	12.0	4.27	4.27	95.73
2	85	12.0	4.08	4.08	95.92
3	85	12.1	4.22	4.22	95.78
4	85	12.7	4.01	4.01	95.99
5	85	9.0	30.61	30.61	69.39
6	85	9.1	24.40	24.40	75.60
7	85	11.5	4.19	4.19	95.81
8	85	8.3	29.38	29.38	70.62
9	85	9.3	28.07	28.07	71.93
10	85	10.2	23.02	23.02	76.98
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.

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Manufacturer: Dongguan Leihuo Medical Device Co., Ltd.

Item Tested: KN95 MASK/CREATIVE GUARD

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Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
11	85	9.7	25.17	25.17	74.83
12	85	9.3	24.23	24.23	75.77
13	85	12.4	4.41	4.41	95.59
14	85	9.8	26.42	26.42	73.58
15	85	9.2	35.64	35.64	64.36
16	85	9.4	20.12	20.12	79.88
17	85	9.9	26.57	26.57	73.43
18	85	9.3	33.83	33.83	66.17
19	85	12.9	4.23	4.23	95.77
20	85	8.2	25.64	25.64	74.36
Minimum Filter Efficiency: 64.36%			Maximum Filter Efficiency: 95.77%		

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Country of Certification: China (GB2626-2006)

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
21	85	10.8	25.89	25.89	74.11
22	85	9.7	25.75	25.75	74.25
23	85	9.1	25.82	25.82	74.18
24	85	9.6	31.35	31.35	68.65
25	85	9.1	27.77	27.77	72.23
26	85	9.3	28.01	28.01	71.99
27	85	9.3	28.54	28.54	71.46
28	85	13.3	4.27	4.27	95.73
29	85	9.2	35.29	35.29	64.71
30	85	13.5	3.94	3.94	96.06
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 $\geq 95\%$
- Suitable for Protection of PM2.5 haze particles, chemicals, dust, air pollution, pollen, food, coal dust, cement dust, and processing manufacturing



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PCS

PRODUCT STANDARD: GB2626-2006

DISPOSABLE



PRODUCT INFORMATION

Product Name: KN95 MASK/CREATIVE GUARD

Main Materials: Non-woven fabric, melt-blown
filtrating, 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.: A2001
MFG. Operator No.: 10063202
Device Listing No.: D375637
Manufacture :
Dongguan Laihao Medical Device Co., LTD
Dongshan Yongshenglu No.47 Room 101, Qishi
Dongguan, Guangdong, 523500, 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: 10066833



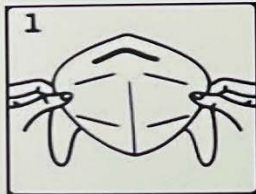
Made in China

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 $\geq 95\%$

INSTRUCTIONS FOR USE

Instructions for Use



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



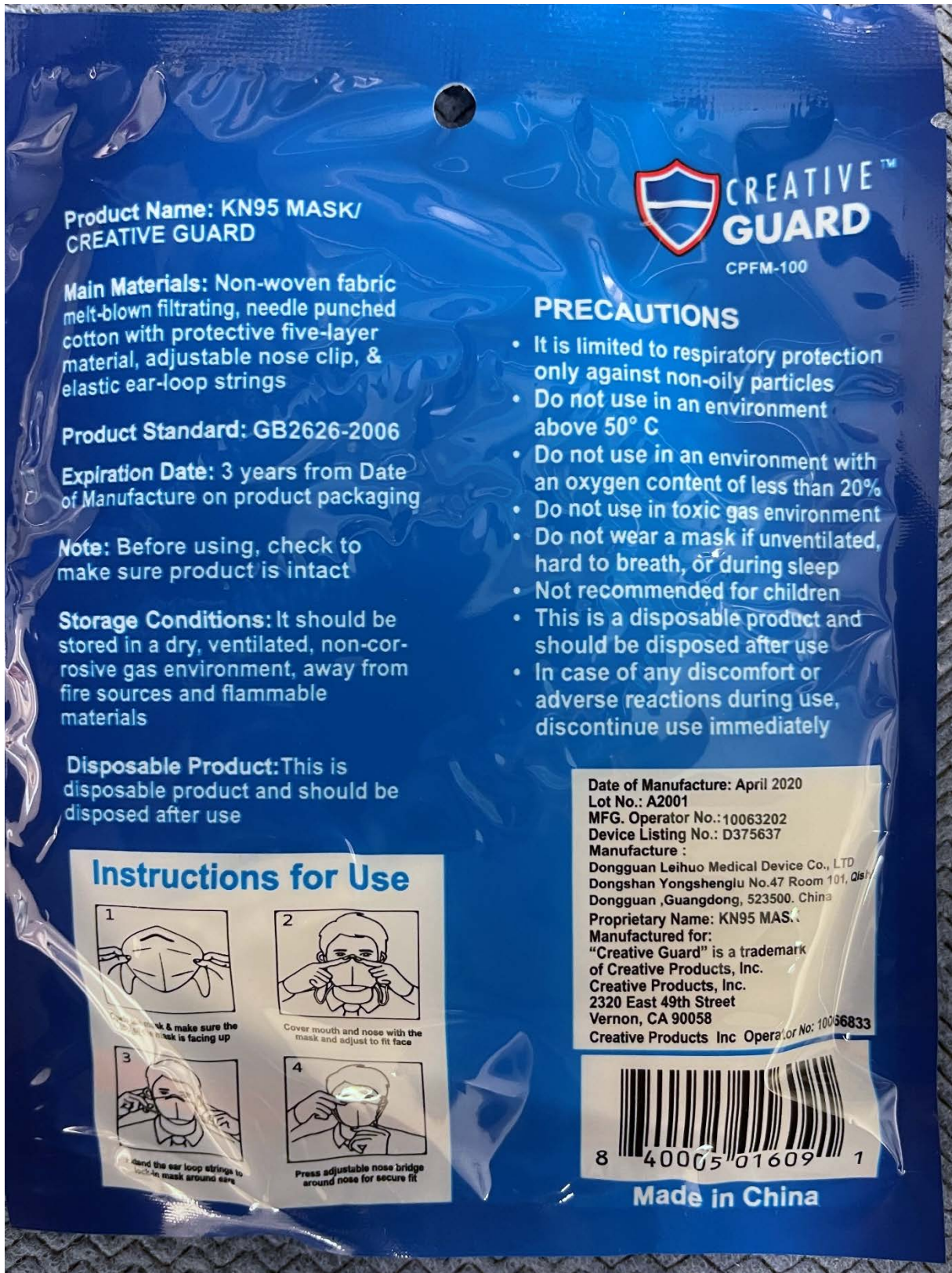
2
Cover mouth and nose with the mask and adjust to fit face



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



4
Press adjustable nose bridge around nose for secure fit



**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

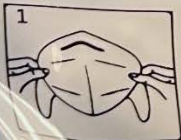
Expiration Date: 3 years from Date of Manufacture on product packaging

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

Instructions for Use



1. Hold the mask by the ear loops & make sure the top of the mask is facing up



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



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



4. Press adjustable nose bridge around nose for secure fit



CPFM-100

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 a mask if unventilated, hard to breath, or during sleep
- Not recommended for children
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Date of Manufacture: April 2020

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MFG. Operator No.: 10063202

Device Listing No.: D375637

Manufacture :

Dongguan Leihuo Medical Device Co., LTD

Dongshan Yongshenglu No.47 Room 101, Dist

Dongguan ,Guangdong, 523500, China

Proprietary Name: KN95 MAS

Manufactured for:

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