

## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Zhangjiagang Zhiyi Medical Health Product Co., Ltd.

Model Tested: COVAFLU ZY-MASK-02

Date Tested: May 10, 2021

These findings pertain to the Zhangjiagang Zhiyi Medical Health Product Co., Ltd., model COVAFLU ZY-MASK-02. The packaging and labeling for this product indicate that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator). The packaging and labeling also indicate that this product meets EN149:2001+A1:2009 (the European standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking).

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 99.87% and 98.63%, respectively. All thirty respirators measured more 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 10, 2021

**Report Prepared:** May 11, 2021

**Manufacturer:** Zhangjiagang Zhiyi Medical Health Product Co., Ltd.

**Item Tested:** COVAFLU ZY-MASK-02

**Country of Certification:** China (GB2626-2006), European (EN149:2001+A1:2009)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	9.9	0.67	0.67	99.33
2	85	10.4	0.59	0.59	99.41
3	85	11.1	0.64	0.64	99.36
4	85	10.0	0.68	0.68	99.32
5	85	10.5	0.57	0.57	99.43
6	85	10.0	0.74	0.74	99.26
7	85	9.7	0.76	0.76	99.24
8	85	10.3	0.61	0.61	99.39
9	85	10.9	0.73	0.73	99.27
10	85	9.3	0.77	0.77	99.23
<b>Minimum Filter Efficiency: 99.23%</b>			<b>Maximum Filter Efficiency: 99.43%</b>		

- 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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Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
11	85	10.6	0.62	0.62	99.38
12	85	9.5	1.16	1.16	98.84
13	85	14.9	0.15	0.15	99.85
14	85	14.6	0.13	0.13	99.87
15	85	15.9	0.17	0.17	99.83
16	85	14.6	0.16	0.16	99.84
17	85	14.7	0.13	0.13	99.87
18	85	14.6	0.15	0.15	99.85
19	85	9.1	0.94	0.95	99.05
20	85	9.1	0.96	0.96	99.04
<b>Minimum Filter Efficiency: 98.84%</b>			<b>Maximum Filter Efficiency: 99.87%</b>		

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Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
21	85	15.2	0.14	0.14	99.86
22	85	9.8	0.84	0.84	99.16
23	85	9.8	0.70	0.70	99.30
24	85	10.0	0.99	0.99	99.01
25	85	10.0	0.76	0.76	99.24
26	85	10.2	0.66	0.66	99.34
27	85	9.9	0.91	0.91	99.09
28	85	8.3	1.37	1.37	98.63
29	85	9.7	0.87	0.87	99.13
30	85	12.6	0.72	0.72	99.28
<b>Minimum Filter Efficiency: 98.63%</b>			<b>Maximum Filter Efficiency: 99.86%</b>		

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# COVAFLU™

## Face Mask

### Product features

Soft flexible material and comfortable elastic ear loops

### Ear loops

70% polyamide / 30% elastane

### Fabric

100% polypropylene

4-ply material

These masks are for personal use in a variety of settings such as home, outdoors and work.

### Instructions for use

For your safety, for correct and effective use of the apparatus, and to avoid hazards, it is essential to read and comply with the following recommendations.

Any use of the face mask requires full understanding and strict observation of the operating instructions. The face mask may only be used for the purposes specified above.

1. Open the bag. Take out the mask by hand and unfold it gently.
2. Bend the nose clip to the shape of your nose.
3. To fit the mask, stretch the two loops carefully and hook them securely behind the ears.
4. Adjust the mask so that it covers the nose and mouth and place the nose clip on the nose bridge. Adjust nose clip if required.
5. Adjust the mask so that the bottom of the mask is under your chin and the top part of the mask is secured at the top of the nose bridge. Make sure the mask forms a tight fit against your skin. The efficiency of the mask and therefore your protection depend on the care taken when fitting.

### WARNING

This mask helps protect against certain particles. Misuse may result in sickness or death. Do not use if the mask makes breathing difficult. Discard immediately if the mask appears dirty or damaged. For correct use see instructions. Always ensure proper fit.

Clinova

Clinova Limited  
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London EC1Y 0SF  
United Kingdom

covaflu.com/usa  
info@clinova.co.uk

CE 2797 (2) For single use only

ZY-MASK-02 Lot No: Z2202004  
Production Date: April 2020  
Expiry Date: April 2023  
Made in China



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## PRODUCT CERTIFICATE

**BRAND:** COVAFLU™

**PRODUCT NAME:** KN95 RESPIRATOR MASK

**MAIN MATERIAL:** 70% NON WOVEN

FABRIC+30% MELT-BLOWN FABRIC

**STANDARD:** GB2626-2006

**CE** 2797

**REFERENCE NO:** ZY-MASK-02

**LOT NO:** Z2202004 **INSPECTOR:** 01

**PRODUCTION DATE:** APR.2020

**EXPIRY DATE:** APR.2023

**MANUFACTURER:** ZHANGJIAGANG ZHIYI

MEDICAL HEALTH PRODUCTS CO., LTD

**ADDRESS:** RENMIN ROAD, LEYU TOWN,

ZHANGJIAGANG, JIANGSU, CHINA



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