

NPPTL COVID-19 Response: International Respirator Assessment

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

Model Tested: COVAFLU ZY-MASK-01

Date Tested: May 6, 2021

These findings pertain to the Zhangjiagang Zhiyi Medical Health Product Co., Ltd., model COVAFLU ZY-MASK-01. 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 99.26% and 86.55%, respectively. Twenty-one respirators measured more than 95% filter efficiency. Nine 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 6, 2021

Report Prepared: May 7, 2021

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

Item Tested: COVAFLU ZY-MASK-01

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 ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	9.0	1.35	1.49	98.51
2	85	10.5	0.74	0.74	99.26
3	85	9.3	11.96	11.96	88.04
4	85	10.1	6.36	6.36	93.64
5	85	8.7	1.18	1.50	98.50
6	85	10.7	8.42	8.42	91.58
7	85	9.7	1.36	1.48	98.52
8	85	9.3	1.57	1.74	98.26
9	85	12.9	13.45	13.45	86.55
10	85	9.0	0.88	1.04	98.96
Minimum Filter Efficiency: 86.55%			Maximum Filter Efficiency: 99.26%		

- 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 ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
11	85	7.8	1.54	1.81	98.19
12	85	7.8	2.18	2.18	97.82
13	85	7.7	2.16	2.16	97.84
14	85	7.9	2.28	2.53	97.47
15	85	10.7	11.55	11.55	88.45
16	85	9.5	2.12	2.37	97.63
17	85	9.6	1.53	1.85	98.15
18	85	17.2	1.58	1.58	98.42
19	85	11.1	4.13	4.13	95.87
20	85	9.8	7.04	7.04	92.96
Minimum Filter Efficiency: 88.45%			Maximum Filter Efficiency: 98.42%		

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Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
21	85	11.4	6.65	6.65	93.35
22	85	8.6	2.06	2.30	97.70
23	85	9.3	1.82	1.82	98.18
24	85	11.4	1.58	1.67	98.33
25	85	9.2	2.52	2.82	97.18
26	85	8.3	1.32	1.56	98.44
27	85	8.7	1.85	1.85	98.15
28	85	10.0	0.75	0.75	99.25
29	85	10.2	5.54	5.55	94.45
30	85	10.7	7.33	7.33	92.67
Minimum Filter Efficiency: 92.67%			Maximum Filter Efficiency: 99.25%		

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COVAFLU™

KN95

Face Mask

10 Face Masks

PIN-MTT-2021-56

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 Limited
2 Sycamore Street
London EC1Y 0SF
United Kingdom

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

② For single use only

ZY-MASK-01 Lot No: Z1202004
Production Date: April 2020
Expiry Date: April 2023
Made in China



NPPTL COVID-19 Response: International Respirator Assessment



MODEL: COVAFLU ZY-MASK-01,
COVAFLU ZY-MASK-02

INTENDED USE

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 mask may only be used for the purposes specified here.

1. Wash your hands before opening the bag.
2. Open the bag. Take out the mask by hand and unfold it gently.
3. Bend the nose clip to the shape of your nose.
4. To fit the mask, stretch the two elastic bands carefully and hook them securely behind the ears.
5. Place the mask so that it covers the nose and mouth, with the nose clip on the nose bridge. Adjust the mask so that the bottom part 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 that the mask forms a tight fit against your skin. The mask's efficiency and therefore your protection depend on the care taken when fitting. With this in mind, adjust the elastic bands for your personal comfort.
6. Once you have fitted the mask, do not touch or adjust it unless you have washed your hands first.

LIABILITY FOR FUNCTION OR DAMAGE

In all cases, liability for the function of the filter passes to the owner or operator. If the respirator face mask is used in a way which does not correspond to the intended use, Clinova cannot be held liable for damage which occurs as a result of failure to follow these instructions. Warranty and liability provisions contained in Clinova's terms of sale and delivery are not modified in any way by the above recommendations.

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

Marketed and distributed by Clinova Limited
2 Sycamore Street, London EC1Y 0SF
info@clinova.co.uk
covafllu.com/usa

CONDITIONS FOR USE

1. Before using this mask, check that it corresponds to your needs in the specific environment of intended use. Failure to do so can put your health or even your life in danger. Seek the advice of a professional (health and safety officer or doctor) to help you to define the protection you need.
2. Failure to follow these instructions can put your health at risk. Please read and adhere to them carefully.
3. This mask does not produce oxygen, so it must be used in a sufficiently ventilated environment. If the oxygen content of the air around you falls below 17%, you will quickly feel dizzy, have difficulty breathing, or even faint. If this happens, you must immediately return to a well-ventilated place.
4. Do NOT use this mask if you don't know the exact nature of any toxin you may encounter. In particular, the mask must not be used near explosive products or in explosive atmospheres.
5. When fitting the mask, extra care should be taken by users who have facial hair or any facial irregularities. In these cases, make sure the mask forms a tight fit against your skin.
6. Do NOT attempt to modify this mask: it has been designed and certified for your safety.
7. This mask is intended for single use. After a maximum of 8 hours' continuous use, dispose of it. The mask will not regain its protective capacities after use.
8. Keep the masks in an area with a maximum humidity level of 70%, and within a temperature range of -25°C to 40°C. The mask can lose its features and protective capacity after three years (see expiry date on the packaging). Do NOT use this mask once the expiry date has passed. Dispose of any masks that have passed their expiry date.
9. In any case and in spite of the whole care brought to this respiratory protective mask by the manufacturer, it is the user's responsibility (and in no case the manufacturer's responsibility) to ascertain the adequacy of the mask in relation to the environmental features where it will be stored and eventually be used. The manufacturer cannot guarantee a precise use length, considering its absence of knowledge of the environment in which the mask will have been stored since leaving the factory, and the features of the environment in which it will be used, such as temperature, pressure, humidity, concentration of filterable particles, and user's facial structure.
10. This mask will protect you only if you follow these recommendations and instructions for use. Failure to use the face mask in accordance with this manual will reduce the effectiveness of the product.

Zhangjiagang Zhiyi Medical Health Product Co. Ltd.

Notified Body and number - 2797

BSI Group The Netherlands B.V.

John M. Keynesplein 9,

1066 EP Amsterdam

The Netherlands

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PRODUCT CERTIFICATE

BRAND: COVAFLU

PRODUCT NAME: KN95 / FFP2 RESPIRATOR
MASK

MAIN MATERIAL: 70% NON WOVEN
FABRIC+ 30% MELT-BLOWN FABRIC

STANDARD:

GB2626-2006/EN149:2001+A1:2009

CE 2797

REFERENCE NO: ZY-MASK-01

LOT NO: 202004 **INSPECTOR:** 01

PRODUCTION DATE: APR.2020

EXPIRY DATE: APR.2023

MANUFACTURER: ZHANGJIAGANG ZHIYI

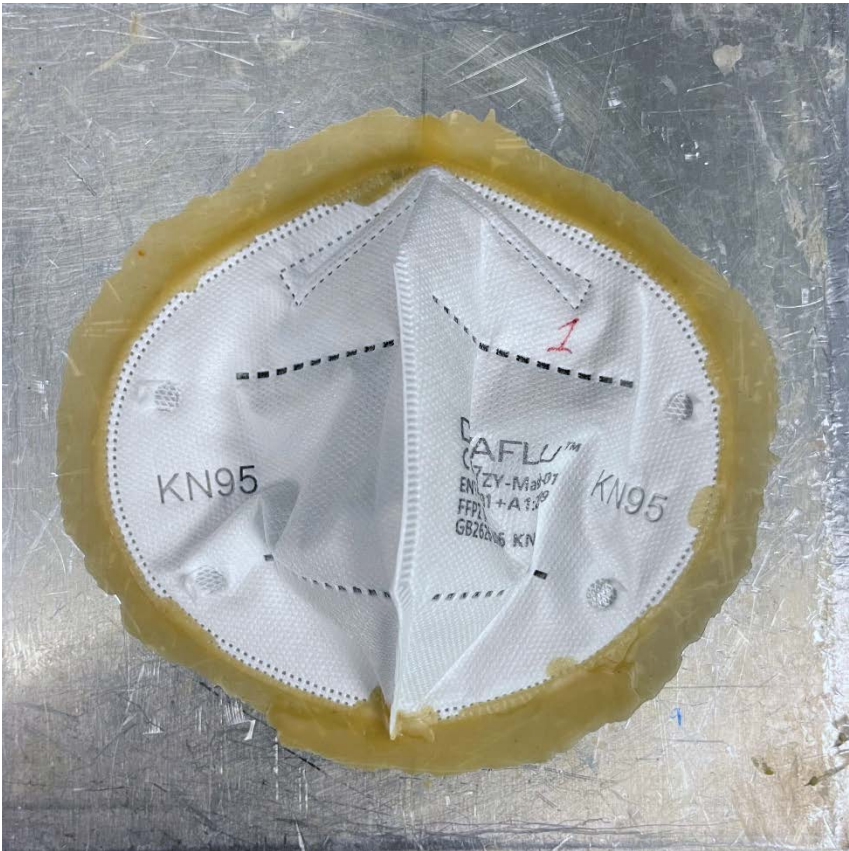
MEDICAL HEALTH PRODUCTS CO., LTD

ADDRESS: RENMIN ROAD, LEYU TOWN,
ZHANGJIAGANG, JIANGSU, CHINA

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