

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangzhou Ouslikang Medical Equipment Co., Ltd.

Model Tested: KZ-002-1-USA

Date Tested: May 18, 2021

These findings pertain to the Guangzhou Ouslikang Medical Equipment Co., Ltd., model KZ-002-1-USA. The packaging for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Ten 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 56.05% and 16.95%, respectively. All ten 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 18, 2021

Report Prepared: May 18, 2021

Manufacturer: Guangzhou Ouslikang Medical Equipment Co., Ltd.

Item Tested: KZ-002-1-USA

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	4.1	75.28	78.86	21.14
2	85	4.3	75.41	76.17	23.83
3	85	4.5	81.06	81.06	18.94
4	85	6.8	51.23	51.23	48.77
5	85	4.6	68.05	68.05	31.95
6	85	6.1	70.10	70.10	29.90
7	85	4.6	67.54	67.54	32.46
8	85	6.2	59.48	59.72	40.28
9	85	4.9	83.05	83.05	16.95
10	85	8.4	43.95	43.95	56.05
Minimum Filter Efficiency: 16.95%			Maximum Filter Efficiency: 56.05%		

- 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 wear:

1. Hold the earloops respectively with your hands to make the nose clip over the nose and the mask against the chin.
2. Hang the earloops on the ears and adjust them until you feel comfortable.
3. Press the nose clip with your fingers from the central part to both sides so as to make the mask closely contact with your face.
4. Cover the mask with both hands and compress at both direct and vertical direction to ensure the tightness of the mask.
5. Check the tightness of the mask on the face before entering the work area.

Product name: Protective face mask
Main materials: non-woven fabrics
Size: appx. 15.3x10.6cm
Model no. : KZ-002-1-USA

Applicable targets : pollen, dust, bacteria
Quantity: 10 pieces/bag
Period of validity: two years

Manufacturer: Guangzhou Ousilikang Medical Equipment Co., Ltd.
Place of origin: guangzhou city, guangdong province
Distributor: WINTRAD GROUP LLC (USA)
Add: 3907 Prince Street Flushing, NY 11354 (USA)


Notes:

1. Make sure that the overall appearance of the mask should be free from damage or pollution before use, the earloops should have good elasticity and the nose clip should be free from damage or fracture.
2. For masks with respiratory valve, check whether the valve plate falls off or is damaged before use.
3. When you are in dyspnea, dizziness or feel uncomfortable, please leave the contaminated area immediately.
4. When the respiratory resistance of the mask is not in function, replace the mask immediately.

MADE IN CHINA



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Winrad 合格证/certificate

产品名称: KN95口罩 (非医用)
Product name: KN-95 protective mask (non-medical)
产品型号/Model no.: KZ-001-2-USA
产品规格/Size: 15.3x10.6cm
材 料: 无纺布、熔喷布
material: Non-woven fabric&Melt-blown nonwovens
执行标准/Standard conformity: GB2626-2006
包装规格: 10只/袋 Quantity: 10 pieces / bag
有效期: 2年 Period of validity: two years
生产日期/Date of production: 20200425
生产批次/Batch No.: 202004
适合范围: 本产品不得用于发热门诊、隔离病房、隔离留观病房、手术室、隔离重症监护室等区域。
Suitable range: This product shall not be used in fever clinic, isolation ward, isolation observation ward, operating room, isolation intensive care unit, etc.
生产商: 广州欧斯利康医疗器械股份有限公司
Manufacturer: Guangzhou Ousilikang Medical Equipment Co., Ltd.
生产地址: 广州市白云区白云湖街大湖北路牌坊旁地段大朗商贸城自编二路A1号
Address: No A1, Zibian II, Dalang Trade City, Paifang Section, Dalang North Road, Baiyunhu Street, Baiyun District, Guangzhou
经销商 (美国) /Distributor: WINTRAD GROUP LLC (USA)
地址 (美国) / Add: 3907 Prince Street Flushing, NY 11354 (USA)

请以中文为准 THE CHINESE VERSION SHALL GOVERN

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