

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Elizabeth (Guangzhou) Medical Technology Co., Ltd.

Model Tested: KN95 Protective Mask

Date Tested: September 30, 2020

These findings pertain to the Elizabeth (Guangzhou) Medical Technology Co., Ltd., model KN95 Protective Mask. 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 a 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 56.20% and 25.20%, respectively. All ten respirators measured less than 95%.

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: September 30, 2020

Report Prepared: September 30, 2020

Manufacturer: Elizabeth (Guangzhou) Medical Technology Co., Ltd.

Item Tested: KN95 Protective Mask

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	8.7	50.0	50.0	50.00
2	85	10.6	48.2	48.2	51.80
3	85	8.6	44.3	44.3	55.70
4	85	8.3	44.0	43.8	56.20
5	85	5.6	65.2	66.8	33.20
6	85	3.9	73.8	74.8	25.20
7	85	6.6	68.1	69.3	30.70
8	85	6.8	61.9	62.4	37.60
9	85	5.5	63.5	63.5	36.50
10	85	7.4	47.8	47.8	52.20
Minimum Filter Efficiency: 25.20%			Maximum Filter Efficiency: 56.20%		

- 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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Product Parameters

Product Parameters: KN95 Protective Mask
Main Material: Nonwoven Fabric, Meltblown Fabric, Needle-punched Cotton.
Production level: KN95
Expiration date: 3 Years.
Executive Standard: GB2626-2006
See the packaging indication for production batch number and expiration date.
Manufacturer: Elizabeth (Guangzhou) Medical Technology Co., Ltd.
Address: RM.201, No. 10 Luoyong North Road, Songzhou Street, Baiyun District, Guangzhou
Contact: 020-81193119
Postcode: 510080

Precautions

- 1: If this package is damaged. It is forbidden to use the masks. It is limited to respiratory protection against non-oily particles only.
- 2: It is recommended to store in dry, ventilated, non-corrosive gas environment below a humidity of 80%. Keep away from ignition sources and flammable materials.
- 3: This product is not applicable to special industries such as anoxic environment, underwater operation, fire control and industrial dust protection or to respiratory protection of infants.
- 4: Do not wear the mask if in a ventilated, hard breathing or during sleep.
- 5: People with abnormal heart or lung functions should not use masks with caution.
- 6: If the mask is damaged or you feel respiratory resistance is obviously increased, replace it in time.
- 7: In case of any discomfort or adverse reaction during use, discontinue the use immediately.
- 8: Do not reuse

Non-Applicable Scenes

- Do not use in environment above 50°C.
- Do not use in environment with oxygen content of below 20%.
- Do not use in toxic gas environment.
- Not recommended for children, pregnant women and the elderly.



How to use



- 1: Open the mask to make the nose clip at the top, and pull the ear straps with both of your hands
- 2: Hold the mask against your chin to completely cover your nose and mouth
- 3: Pull the ear straps behind your ears and adjust them to make you feel comfortable
- 4: Use both of your hands to adjust the shape of the nose clip. Place your fingers in the middle of the nose clip and press it inward while moving your fingertips along both sides of the nose clip until it is pressed to fit the bridge of your nose. (Making the nose clip get seal with only one hand may affect the tightness of the mask).
- 5: Cover the mask with your hand and exhale vigorously. If you feel the air is escaping from the nose clip, it is required to tighten the nose clip; if the air escapes from the edge of the mask, readjust the headband to ensure tightness

Inspection Method

Before use, check whether the packaging of the masks is damaged and components are intact. In case of any stain or damage, discontinue use immediately. Before entering the work area, it is required to check the air tightness of the mask. If you feel a leak, please wear it again according to the instructions for how to wear mask. You can enter the work area only after feeling no leakage. (If you feel the respiratory resistance is obviously increased or mask falls short of the standard for use, it is recommended to replace the mask immediately).

This dust mask is used to protect non-oily suspended particles. Filtration efficiency ≥95%

Do not use if package is damaged: Please refer to the manual before use and use the mask correctly!

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伊丽莎白
ELIZABETH

合格证

Certificate of conformity

品名：KN95防护口罩（非医用）
Product Name: KN95 protective mask (non-medical)

产品原料：无纺布，熔喷布，热风棉
Product raw materials: non-woven fabric, melt-blown fabric, hot air cotton

产品性能：PFE≥95% 达到KN95级别
Product performance: PFE≥95% reaches KN95 level

执行标准：EN 149:2001+A1:2009
Executive Standard GB2626-2006

规格：折叠后145X100mm
Specifications: 145X100mm after folding

产品批次：2020_1-A
Product batch

生产日期：18/04/2020
Production Date

检验：合格 有效期：3年
Inspection: qualified Validity: 3 years

厂家：伊丽莎白(广州)医疗科技有限公司
Manufacturer: Elizabeth (Guangzhou) Medical Technology Co., Ltd.

厂址：广州市白云区松洲街螺涌北路10号201
Address: 201, No. 10 Luoyong North Road, Songzhou Street, Baiyun District, Guangzhou

中国制造/Made in china



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