NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangdong Zhizhen Biological Medicine Co., Ltd.
Model Tested: KN95 Three-Dimensional Protective Respirator
Date Tested: May 15, 2020

These findings pertain to the Guangdong Zhizhen Biological Medicine Co., Ltd., KN95 Three-Dimensional Protective Respirator. 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 96.50% and 88.60%, respectively. Six respirators measured more than 95%. Four 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 respirator's 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

NPPTL
National Personal Protective Technology Laboratory

Test: Modified TEB-APR-STP-0059

Date Tested: May 15, 2020

Report Prepared: May 16, 2020

Manufacturer: Guangdong Zhizhen Biological Medicine Co., Ltd.

Item Tested: KN95 Three-Dimensional Protective Respirator

Country of Certification: China (GB2626-2006)

Pictures have been added to the end of this report.

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	13.0	4.53	4.53	95.47
2	85	21.0	11.4	11.4	88.60
3	85	13.8	4.15	4.15	95.85
4	85	16.1	3.50	3.50	96.50
5	85	20.5	6.08	6.08	93.92
6	85	18.7	9.16	9.16	90.84
7	85	14.4	4.11	4.11	95.89
8	85	18.8	5.62	5.62	94.38
9	85	16.2	4.22	4.22	95.78
10	85	13.6	4.81	4.81	95.19
Minimum Filter Efficiency: 88.60			**Maximum Filter Efficiency: 96.50**		

- 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.


DR.MFYAN
PURE AND HEALTHY
MIT-2020-153
KN95 GRADE ANTI-PARTICULATE FILTRATION TECHNOLOGY WAS ADOPTED
ANTIBACTERIAL AND ENVIRONMENT-FRIENDLY FABRIC
WIDEN ELASTIC BAND TO RELIEVE EAR DISCOMFORT
KN95
THREE-DIMENSIONAL PROTECTIVE RESPIRATOR
DISPOSABLE RESPIRATOR
★ Adopting KN95 grade anti-particulate matter filtering technology and antibacterial environmental protection fabric.
★ Effectively filtering and protecting from PM2.5 air particulate matter and bacteria.
1PC / BAG

THREE-DIMENSIONAL PROTECTIVE RESPIRATOR (DISPOSABLE RESPIRATOR) **TYPE: KN95**

Material: electrostatic meltblown cloth, pp spunbond non-woven cloth.

Function: adopting KN95 grade anti-particulate matter filtering technology and antibacterial environmental protection fabric, effectively filtering and protecting from PM2.5 air particulate matter and bacteria.

Scope Of Application: suitable for protection against harmful particles such as dust, PM2.5 haze particles, influenza bacteria, droplets and so on.

How To Wear:

1.Hold the respirator in hand, make the fingertip located in the nose clip, let the earband fall naturally.

2.Put the respirator over the face and make sure that the nose strip of the respirator is close to the nose to ensure tightness.

3. Pull the earband behind the ear.

4. Use two hands to adjust the nose strip to ensure tightness.

Wearing Test:

◇Use your hands to cover the respirator and exhale, if you feel gas leaking from nose location, tighten the nose clip.

◇If air leaks from the edge, readjust the earband to ensure tightness.

Note:

◇ This respirator is maintenance-free. Do not wash it. Do not use a microwave oven to heat it. When the filter cotton is seriously dirty, damaged, or you feel the breathing resistance increases significantly, please replace the respirator in time.

◇To ensure that the respirator is clean and hygienic, avoid touching the inside of the respirator with your hands and wash your hands before wearing the respirator each time.

Recommended Storage Conditions: unopened products are stored in a temperature range of -20°C to 30°C and a relative humidity of less than 80%.

Note: the wearer must read and understand these instructions before using. Please save these instructions for reference.

Manufacturer: Guangdong Zhizhen Biological Medicine Co., Ltd.
Address: No. 5 South Street, Datian First Team, Minzhu Village, Tanbu Town, Huadu District, Guangzhou
Implementation standard: GB 2626-2006 KN95
Hygienic standard: GB 15979-2002
Production date: see packaging label
Shelf life: 3 years (unopened)
Place of origin: Guangzhou, Guangdong, China
Phone: +8620-37713902 Postcode: 510820
Web: http://www.drmfyan.cn
Email: 2416659392@qq.com

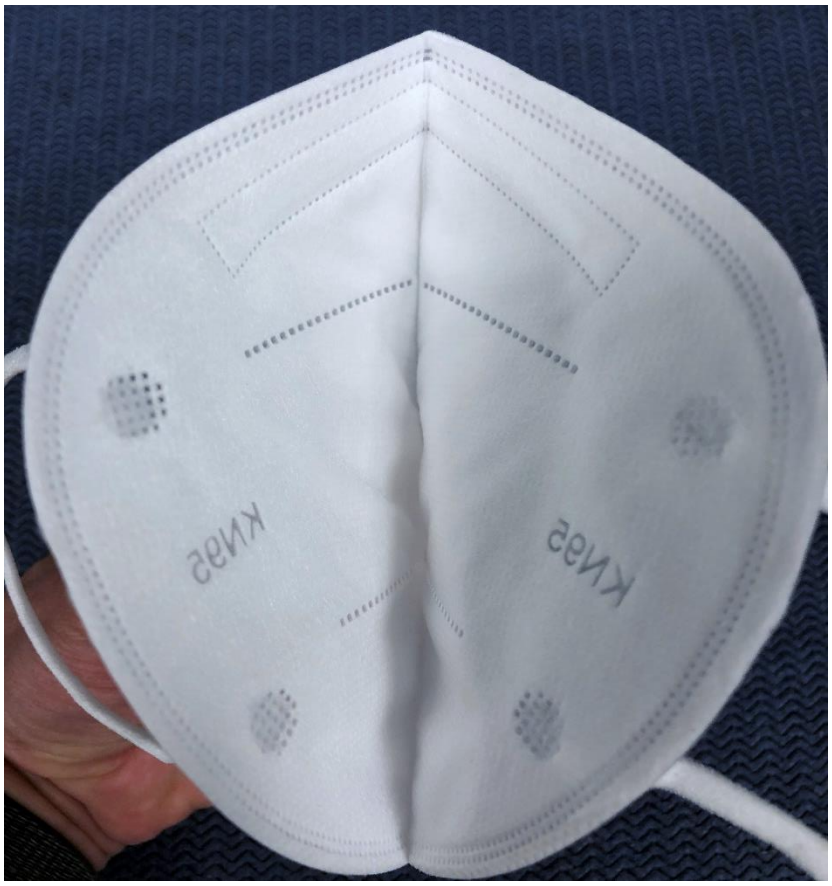
Non-medical

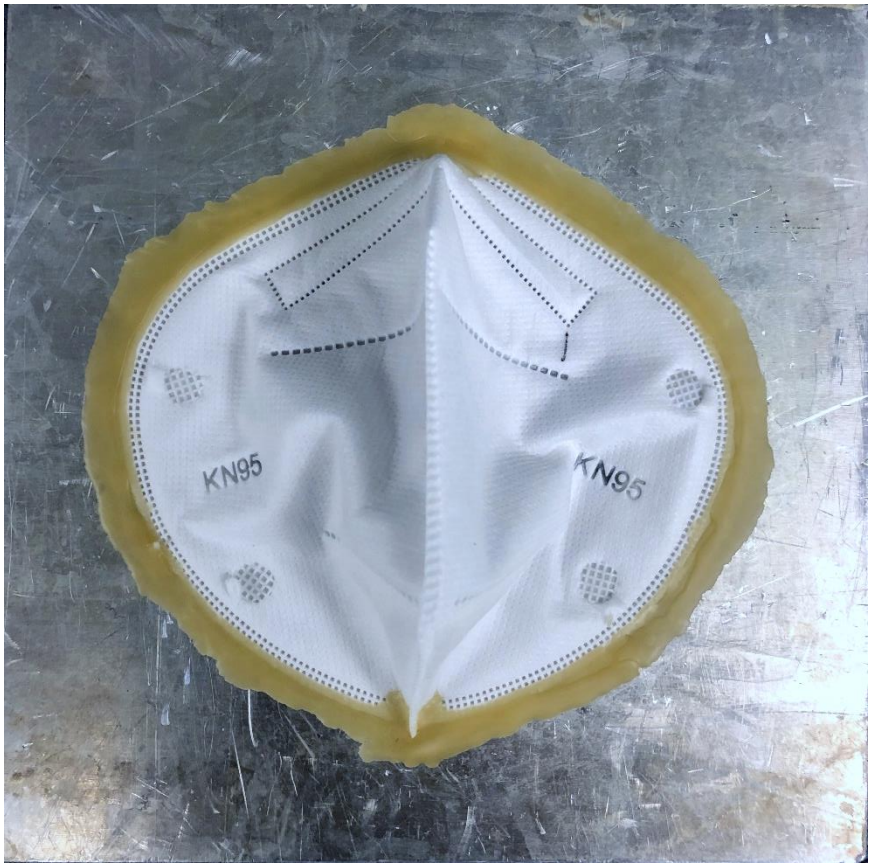
MADE IN CHINA

6 973076 760342

NPPTL COVID-19 Response: International Respirator Assessment

NPPTL COVID-19 Response: International Respirator Assessment





NPPTL COVID-19 Response: International Respirator Assessment