

## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangdong Zhizhen Biological Medicine Co., Ltd.

Model Tested: Three-Dimensional Protective Respirator

Date Tested: June 5, 2020

These findings pertain to the Guangdong Zhizhen Biological Medicine Co., Ltd., 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 46.70% and 25.00%, respectively. All ten respirators measured less than 95% 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 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**

**Test:** Modified TEB-APR-STP-0059

**Date Tested:** June 5, 2020

**Report Prepared:** June 5, 2020

**Manufacturer:** Guangdong Zhizhen Biological Medicine Co., Ltd.

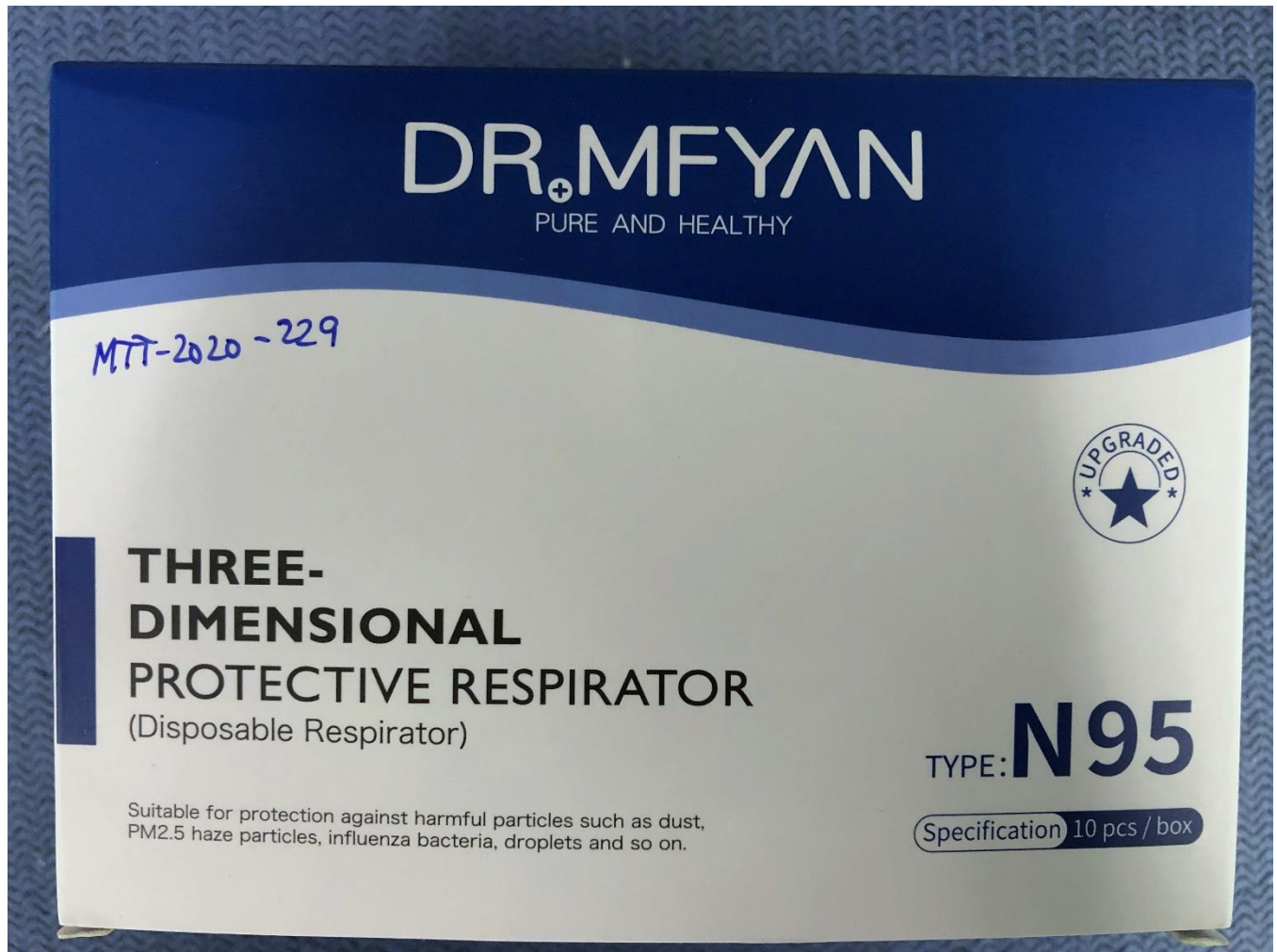
**Item Tested:** Three-Dimensional Protective Respirator

**Country of Certification:** China (GB2626-2006)

Pictures have been added to the end of this report.

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	10.3	59.3	59.3	40.70
2	85	9.7	53.3	53.3	46.70
3	85	10.4	57.0	57.0	43.00
4	85	7.4	73.7	73.7	26.30
5	85	6.8	68.8	68.8	31.20
6	85	7.1	75.0	75.0	25.00
7	85	9.6	60.7	60.7	39.30
8	85	9.7	55.8	55.8	44.20
9	85	10.0	58.5	58.5	41.50
10	85	11.0	59.3	59.3	40.70
<b>Minimum Filter Efficiency: 25.00</b>			<b>Maximum Filter Efficiency: 46.70</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.



### **THREE-DIMENSIONAL PROTECTIVE RESPIRATOR(DISPOSABLE RESPIRATOR)**

**Type:** N95      **Specification:** 10 pcs / box

**Main materials:** 16% non-woven cloth, 68% hot melt cotton, 16% melt-blown cloth.

**Function:** adopting N95 grade anti-particulate matter filtering technology and antibacterial environmental protection fabric, effectively filtering and protecting from PM2.5 air particulate matter and bacteria. N95 is the American NIOSH anti-particulate respirator for occupational use in the United States under the standard test conditions for aerodynamic diameter of 0.3 micron filtration rate of at least 95%.

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

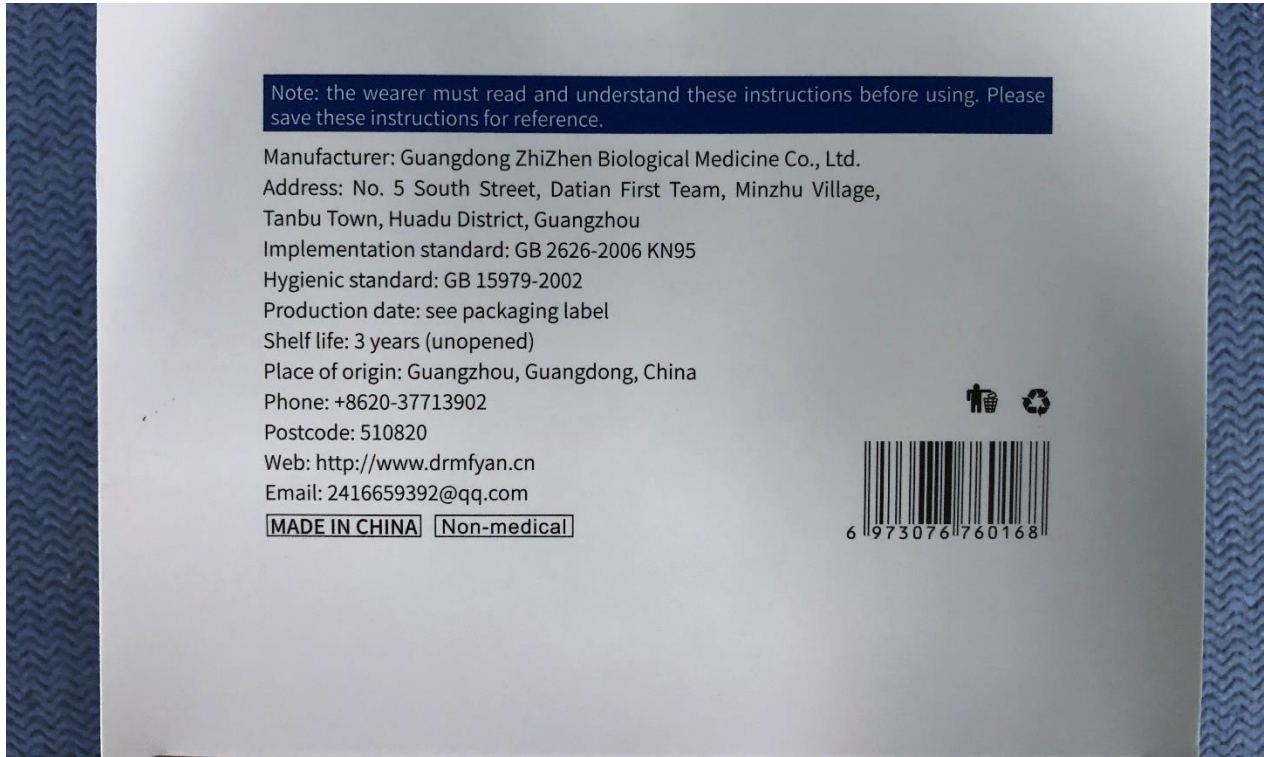
**Note:** ◇This respirator is maintenance-free. Do not wash it. Do not use a microwave oven to heat it. When the filter cotton is seriously dirty, damaged, or you feel the breathing resistance increases significantly, please replace the respirator in time. ◇Not recommended for children under three due to low lung capacity. ◇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%.

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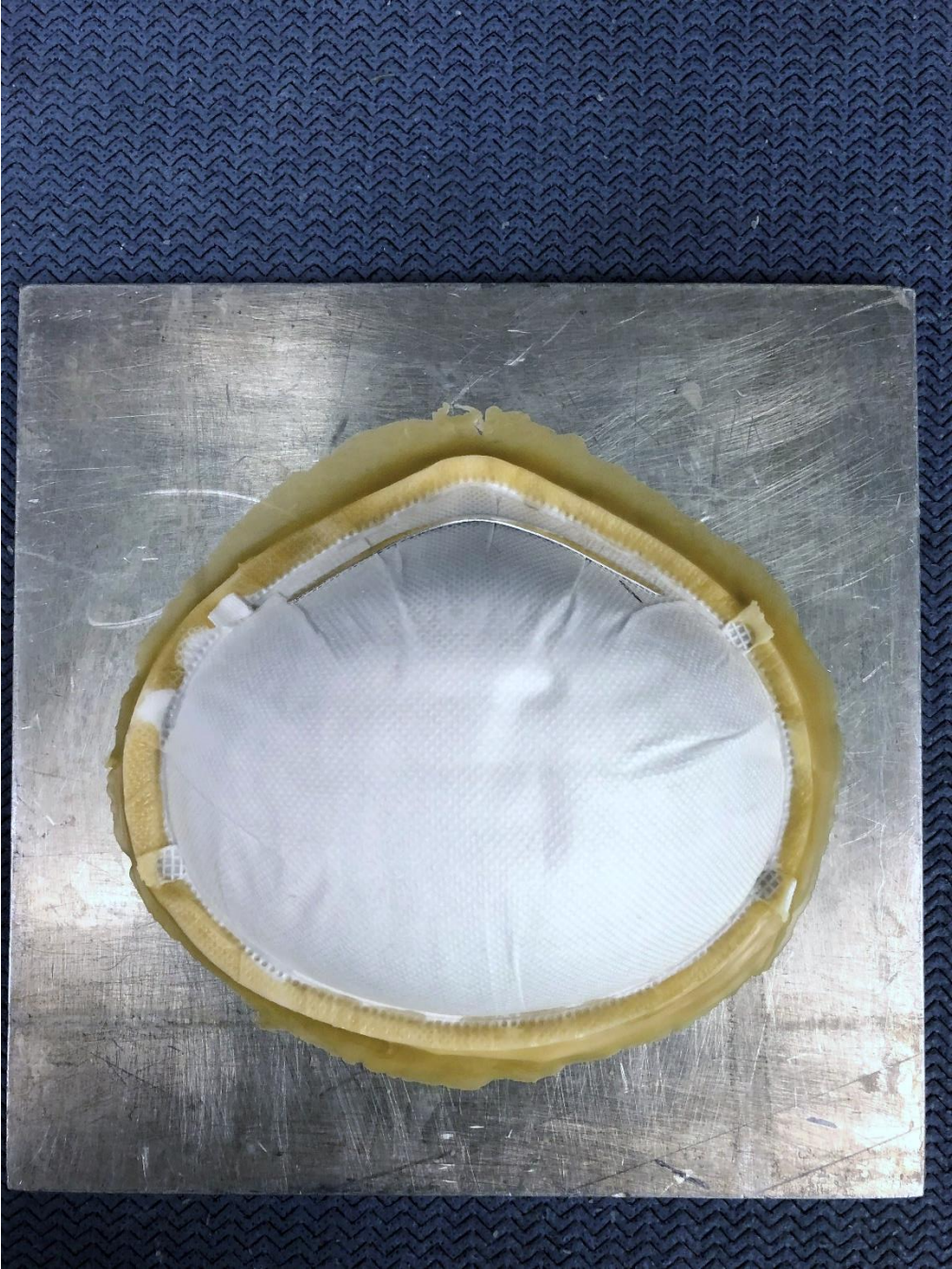


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