## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangdong Medical Technology Co., Ltd.

Model Tested: 1MED-4LPR1 Date Tested: August 12, 2020

These findings pertain to the Guangdong Medical Technology Co., Ltd., model 1MED-4LPR1. The packaging and labeling 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 98.76% and 96.91%, respectively. All ten respirators measured more 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 <u>Crisis Capacity Strategies (during known shortages)</u>.

## **Evaluation of International Respirators**



Pictures have been added to the

end of this report.

Test: Modified TEB-APR-STP-0059

Date Tested: August 12, 2020

Report Prepared: August 17, 2020

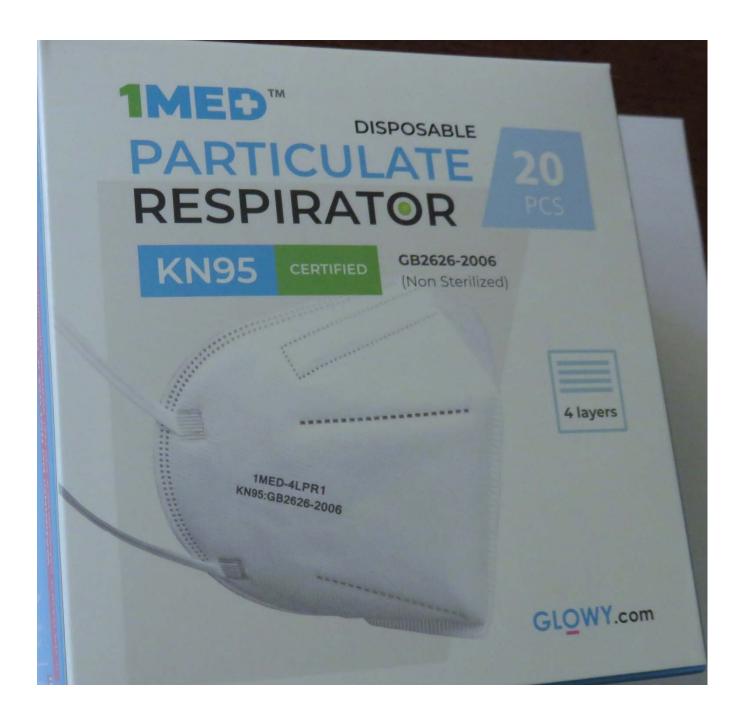
Manufacturer: Guangdong Medical Technology Co., Ltd.

Item Tested: 1MED-4LPR1

Country of Certification: China (GB2626-2006)

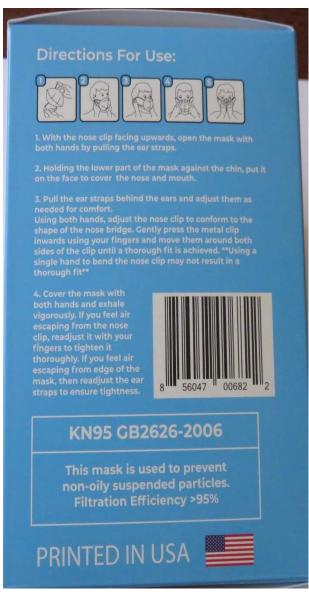
| Filter | Flow Rate<br>(LPM)  | Initial Filter<br>Resistance<br>(mmH₂O) | Initial Percent<br>Leakage<br>(%) | Maximum<br>Percent Leakage<br>(%) | Filter Efficiency<br>(%) |
|--------|---------------------|---|-----------------------------------|-----------------------------------|--------------------------|
| 1      | 85                  | 28.3                                    | 3.09                              | 3.09                              | 96.91                    |
| 2      | 85                  | 20.0                                    | 1.77                              | 1.77                              | 98.23                    |
| 3      | 85                  | 25.0                                    | 1.98                              | 1.98                              | 98.02                    |
| 4      | 85                  | 24.5                                    | 2.41                              | 2.41                              | 97.59                    |
| 5      | 85                  | 27.3                                    | 1.46                              | 1.46                              | 98.54                    |
| 6      | 85                  | 30.0                                    | 2.21                              | 2.21                              | 97.79                    |
| 7      | 85                  | 22.4                                    | 1.30                              | 1.30                              | 98.70                    |
| 8      | 85                  | 30.6                                    | 1.60                              | 1.60                              | 98.40                    |
| 9      | 85                  | 22.5                                    | 1.64                              | 1.64                              | 98.36                    |
| 10     | 85                  | 20.3                                    | 1.24                              | 1.24                              | 98.76                    |
| Ŋ      | Minimum Filter Effi | ciency: 96.91%                          | Maximum Filter Efficiency: 98.76% |                                   |                          |

- 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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## **Directions For Use:**



- With the nose clip facing upwards, open the mask with both hands by pulling the ear straps.
- Holding the lower part of the mask against the chin, put it on the face to cover the nose and mouth.
- Pull the ear straps behind the ears and adjust them as needed for comfort.

Using both hands, adjust the nose clip to conform to the shape of the nose bridge. Gently press the metal clip inwards using your fingers and move them around both sides of the clip until a thorough fit is achieved. "Using a single hand to bend the nose clip may not result in a thorough fit"

4. Cover the mask with both hands and exhale vigorously. If you feel air escaping from the nose clip, readjust it with your fingers to tighten it thoroughly. If you feel air escaping from edge of the mask, then readjust the ear straps to ensure tightness.



### KN95 GB2626-2006

This mask is used to prevent non-oily suspended particles. Filtration Efficiency >95%

## Before using the mask, Perform these 3 simple checks to ensure:

- The overall appearance of the mask is clean without any damage or pollutants on the surface.
- 2. The ear straps are not damaged and have good elasticity.
- The nose clip is not damaged or broken.

Do Not Use the mask if any of the above checks fail.



PLEASE DISPOSE OFF IN A RECYCLE BIN AFTER USE. PLEASE BE CONSIDERATE TO OTHERS & OUR PLANET EARTH.

# Manufactured for:

QYK BRANDS, LLC. Garden Grove, California USA

### Questions / Comments:

888-586-6386 support@glowy.com

#### Manufactured by:

Guangdong Medical Technology Co. Ltd Guangzhou China

Shelf Life: 2 Years from date of manufacture Batch number and production date printed on this side.

#### WARNING! DO NOT USE IF PACKAGE IS DAMAGED.

IF THE MASK IS DAMAGED OR IF YOU FEEL INCREASED RESPIRATORY RESISTANCE, REPLACE THE MASK.









