NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Zhengzhou Ruipu Medical Technology Co., Ltd.
Model Tested: RIPE DOCTORS KN95 Respirator
Date Tested: May 29, 2020

These findings pertain to the Zhengzhou Ruipu Medical Technology Co., Ltd., RIPE DOCTORS KN95 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 96.58% and 95.86%, 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 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)](#).
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Evaluation of International Respirators

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

**Date Tested:** May 29, 2020

**Report Prepared:** May 30, 2020

**Manufacturer:** Zhengzhou Ruipu Medical Technology Co., Ltd.

**Item Tested:** RIPE DOCTORS KN95 Respirator

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

<table>
<thead>
<tr>
<th>Filter</th>
<th>Flow Rate (Lpm)</th>
<th>Initial Filter Resistance (mmH2O)</th>
<th>Initial Percent Leakage (%)</th>
<th>Maximum Percent Leakage (%)</th>
<th>Filter Efficiency</th>
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<tbody>
<tr>
<td>1</td>
<td>85</td>
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</table>

**Minimum Filter Efficiency:** 95.86  **Maximum Filter Efficiency:** 96.58

- 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.

Pictures have been added to the end of this report.
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**Product structure of filter element for nano-fiber protective mask**

The product is composed of spunbonded protective layer, primary filter layer (PP melt-blown cotton), high-efficiency filter layer (nano-fiber membrane) and spunbonded support layer by ultrasonic wave (as shown in Figure 1). The diameter of melt-blown non-woven fiber is 2-10 μm, which can block large particulate matter with more than 2 μm; the fiber diameter of nano-fiber membrane is 100-200 nm, and the formed three-dimensional porous structure can effectively separate 0.5 μm, pollen, virus and other pollutants.

**Development of antivirus protective mask**

The development of nano-fiber protective mask with virus protection function has been completed. This protective mask adopts the gradient filtration effect of melt-blown static cotton and nano-fiber composite structure from micron-scale to nano-scale. The filtration efficiency of 0.3μm standard particulate matter is more than 99.9% (test condition on the full-automatic filter material test system TS18130-A, there are wind speed and flow rate with 15 L/min and 0.3 μm NaCl artificial dust), the filtration efficiency is still stable with more than 80% after the static electricity is completely removed.

**The key technology of preparation of nano-fiber which can effectively protect against virus**

That can effectively protect and kill viruses is the preparation of nano-fibers with a diameter of 50-150 nm by the self-developed linear electrode electrospinning technology. The ultra-thin nonwoven filter materials with a filtration accuracy of 100 nm can be processed with such viruses, oil particle matter, etc.

**New features of filter element for nano-fiber protective mask**

1. **Gradient filtration structure:** The product adopts the composite structure of melt-blown static cotton and nano-fiber to realize the gradient filtration effect from micron scale to nano-scale.

2. **Stable filtration performance:** This product can be applied to all kinds of environments, such as humidity, disinfection and other environments, and can still maintain efficient filtration. This product mainly relies on physical filtration after removing static electricity, the filtration is stable with more than 80%, while the traditional electrostatic melt-blown cotton has only 15-25% filtration efficiency under such static electricity.

3. **High filtration accuracy:** This product uses ultra-fine nano-fibers as the core filtration layer, with the filtering accuracy less than 100nm, which can effectively intercept ultra-fine particles such as protective masky droplets, PM2.5, viruses, oil particulate matter, etc.
PRODUCT FEATURES

- High efficiency protection filter element of nano-fiber
  Can be used again and again 20 times
- Chin no weld folding design Wear more comfortably

KN95
STANDARD SIZE

STORAGE CONDITIONS AND SHELF LIFE

Unopened products should be stored at a temperature of -20 °C to +30 °C and relative humidity below 80%. Validity period is within 5 years from the date of production This product contains no natural rubber ingredients. (see box for production date)

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 xinzheng city, henan province
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CAVEAT

This product is only used for respiratory protection against particles. Misuse can cause illness or even death. If you want learn how to use it properly see the instructions on the box!

WEARING METHOD

1. You should face the mask without the nose clip, the nose clip is located above the mask. Hold the mask on your face with your hand and hold it against your chin.
2. Hang the strap on both ears.
3. Place your fingers in the middle of the metal nose clip, while pressing it inward, move the nose clip to both sides until the nose clip is fully pressed into the bridge of the nose. Holding the mask nose clip with just one hand may affect the fitness of the mask.
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RIPE DOCTORS™

KN95 RESPIRATOR

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生产日期: 2020年04月03日
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