

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Zhengzhou Ruipu Medical Technology Co., Ltd.

Model Tested: KN95 Folding Respirator

Date Tested: June 2, 2020

These findings pertain to the Zhengzhou Ruipu Medical Technology Co., Ltd., KN95 Folding 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 98.18% and 96.19%, 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 \(during known shortages\)](#).

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: June 2, 2020

Report Prepared: June 3, 2020

Manufacturer: Zhengzhou Ruipu Medical Technology Co., Ltd.

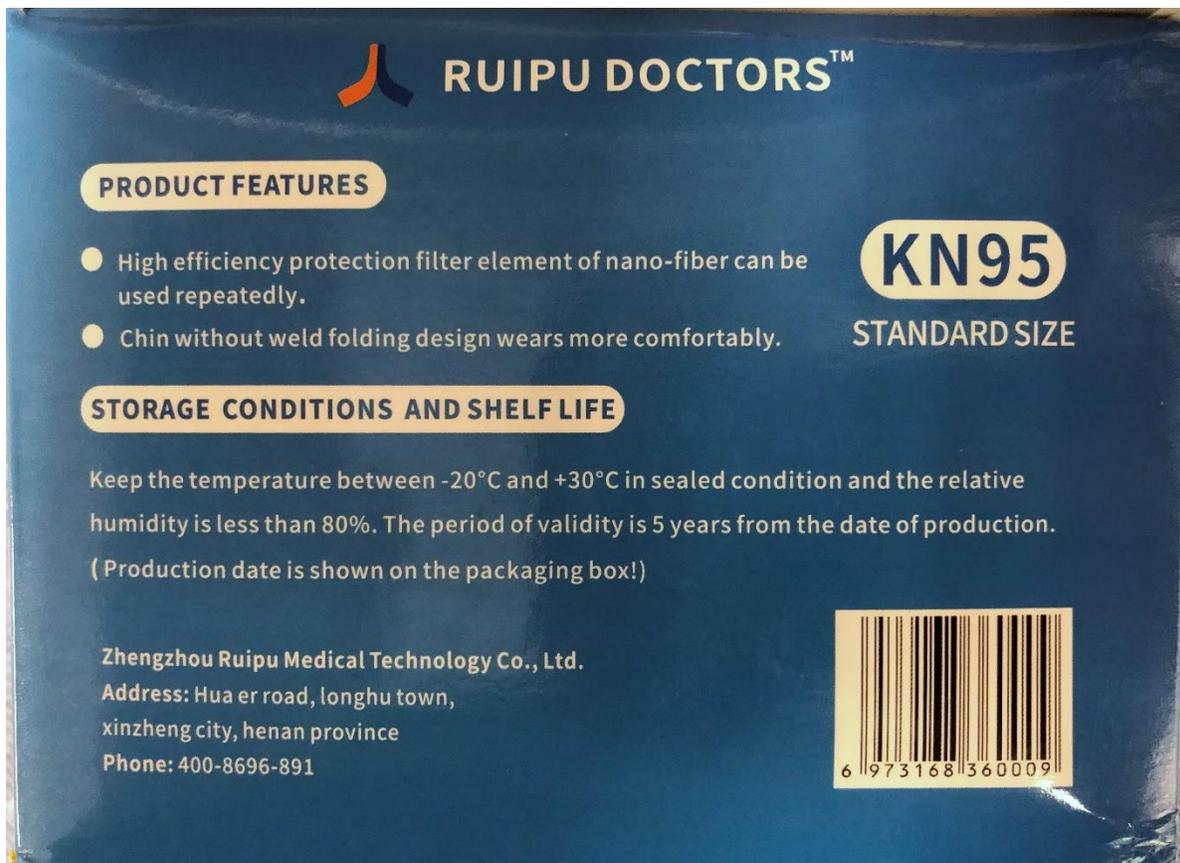
Item Tested: KN95 Folding Respirator

Country of Certification: China (GB2626-2006)

Pictures have been added to the end of this report.

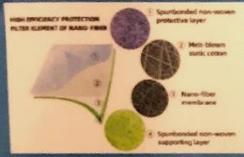
Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	10.9	1.82	1.82	98.18
2	85	11.4	3.67	3.67	96.33
3	85	14.0	2.62	2.62	97.38
4	85	12.0	3.46	3.46	96.54
5	85	11.2	2.23	2.23	97.77
6	85	11.5	3.81	3.81	96.19
7	85	11.1	2.02	2.02	97.98
8	85	10.4	3.17	3.17	96.83
9	85	11.8	2.86	2.86	97.14
10	85	11.2	3.82	3.82	96.18
Minimum Filter Efficiency: 96.19			Maximum Filter Efficiency: 98.18		

- 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 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 supporting 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, harmful substance and other pollutants.

Development of efficient protective respirator

The development of nanofiber respirator with efficient protective 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 0.3 μm standard particulate matter is more than 99.9% (test condition: on the full-automatic filter material test system TS18130A, the wind speed and flow rate is 15 L / min and 0.3 μm NaCl artificial dust), the filtration efficiency is still stable at more than 80% after the complete removal of static electricity.

Nanofiber respirator can effectively enhance protection

The key technology for the preparation of nano-fiber which can be protected effectively is to produce nano-fiber with a diameter of 50-150 nm through the self-developed linear electrode electrostatic spinning technology. With this kind of microfiber as raw materials, the ultra-thin nonwoven filter materials with filtration accuracy of 100 nm can be processed, which can effectively intercept pathogen transmission media such as respiratory droplets, PM2.5, oily particulate 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 pure physical filtration, and the filtration is stable at more than 80%, after the removal of static electricity. However, the filtration efficiency of the traditional electrostatic melt-blown cotton is only 15-25% after removing the 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 respiratory droplets, PM2.5, harmful substance, oily particulate matter etc.

MTT-2020-203

TECHNOLOGY PATENT NO: ZL201811048419.9

RUIPU DOCTORS™
NANOFIBER FILTRATION
RUIPU DOCTORS
ANTI-PARTICULATE MATTER
STAND-UP FOLDING MASK
GB2626-2006 KN95 NON-MEDICAL

0³
OZONE STERILIZATION

EAR HANGING TYPE
1/pack

Protection of haze and particulate matter (PM2.5)

MADE IN CHINA

FILTRATION EFFICIENCY $\geq 95\%$
0.3 μm PARTICULATE MATTER

4 layers protection
Reusable

PASSED ISO9001 PRODUCT QUALITY SYSTEM CERTIFICATION
 ZHENGZHOU RUIPU MEDICAL TECHNOLOGY CO., LTD.

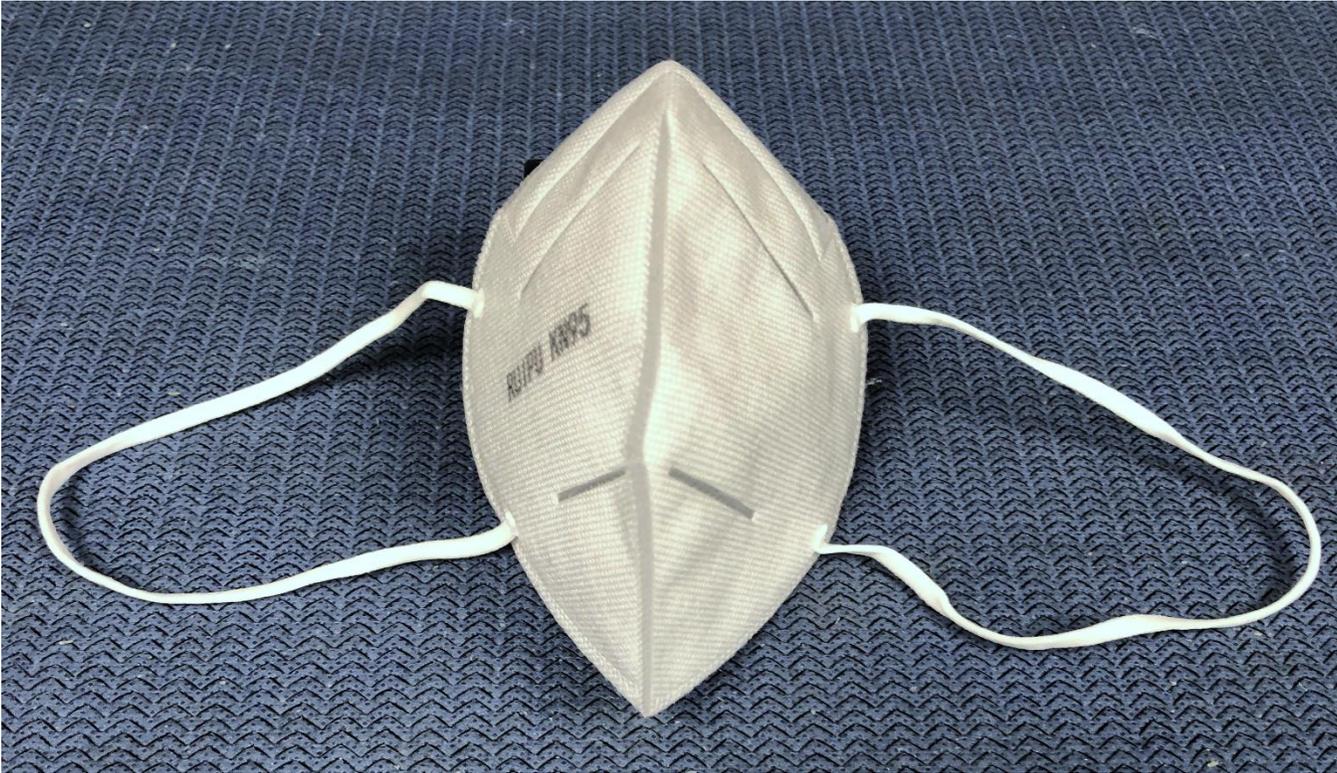
合格证
CERTIFICATE

产品名称: KN95折叠式口罩
 Product Name: KN95 Folding Respirator
 产品规格: 15.4*10.8 cm
 Specification:
 产品品牌: 锐普医生/Ruipu Doctors
 Product Brand:
 主要材料: 30%无纺布, 40%熔喷棉, 30%纳米纤维层
 Ingredients: 30% of non-woven fabric, 40% of melt-blown cotton, 30% of nano-fiber layer
 执行标准: GB2626-2006
 Carried Standard:
 生产日期: 2020/04/26
 Production Date:
 生产批号: 20200426
 Batch Number:
 检验日期: 2020/04/26
 Inspection Date:
 保质期: 5年/5 years
 shelf life:
 生产商: 郑州锐普医疗科技有限公司
 Manufacturer: Zhengzhou Ruipu Medical Technology Co., Ltd
 生产地址: 河南省新郑市龙湖镇华二路
 Address: Hua'er Road, Longhu Town, Xinheng City, Henan Province
 检验员: 检验员01
 Inspector: Inspector 1

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