

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shengguang Medical Instrument Co., Ltd.

Model Tested: Medical Protective Mask

Date Tested: May 22, 2020

These findings pertain to the Shengguang Medical Instrument Co., Ltd., Medical Protective Mask. The packaging for these respirators indicates they meet GB19083-2010 (the Chinese standard for Technical Requirements for Protective Face Mask for Medical Use).

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 99.53% and 99.22%, 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: May 22, 2020

Report Prepared: May 26, 2020

Manufacturer: Shengguang Medical Instrument Co., Ltd.

Item Tested: Medical Protective Mask

Country of Certification: China (GB19083-2010)

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 | 11.3 | 0.50 | 0.50 | 99.50 |
| 2 | 85 | 11.3 | 0.56 | 0.56 | 99.44 |
| 3 | 85 | 11.4 | 0.55 | 0.55 | 99.45 |
| 4 | 85 | 11.0 | 0.51 | 0.51 | 99.49 |
| 5 | 85 | 11.4 | 0.57 | 0.57 | 99.43 |
| 6 | 85 | 11.7 | 0.63 | 0.63 | 99.37 |
| 7 | 85 | 11.5 | 0.47 | 0.47 | 99.53 |
| 8 | 85 | 11.8 | 0.70 | 0.70 | 99.30 |
| 9 | 85 | 12.5 | 0.78 | 0.78 | 99.22 |
| 10 | 85 | 11.7 | 0.62 | 0.62 | 99.38 |
| Minimum Filter Efficiency: 99.22 | | | Maximum Filter Efficiency: 99.53 | | |

- 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.

MTT-2020-1722



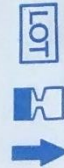
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注册证编号:豫械注准20182140825
产品技术要求编号:豫械注准20182140825
本企业通过ISO 9001、ISO 13485质量体系认证
本产品符合GB19083-2010标准要求。

医用防护口罩

型号规格:鸭嘴形



- 供医疗工作环境下,过滤空气中的颗粒物、阻隔飞沫、血液、体液、分泌物用。
- 本产品经环氧乙烷灭菌,无菌。有效期两年。
- 本产品密封包装,包装破损禁止使用。
- 本产品应储存在无腐蚀性气体和通风良好、清洁的室内。
- 生产批号即生产日期,其他内容详见说明书。



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STERILE EO

STERILE

过滤效率等级:1级
(过滤效率≥95%)

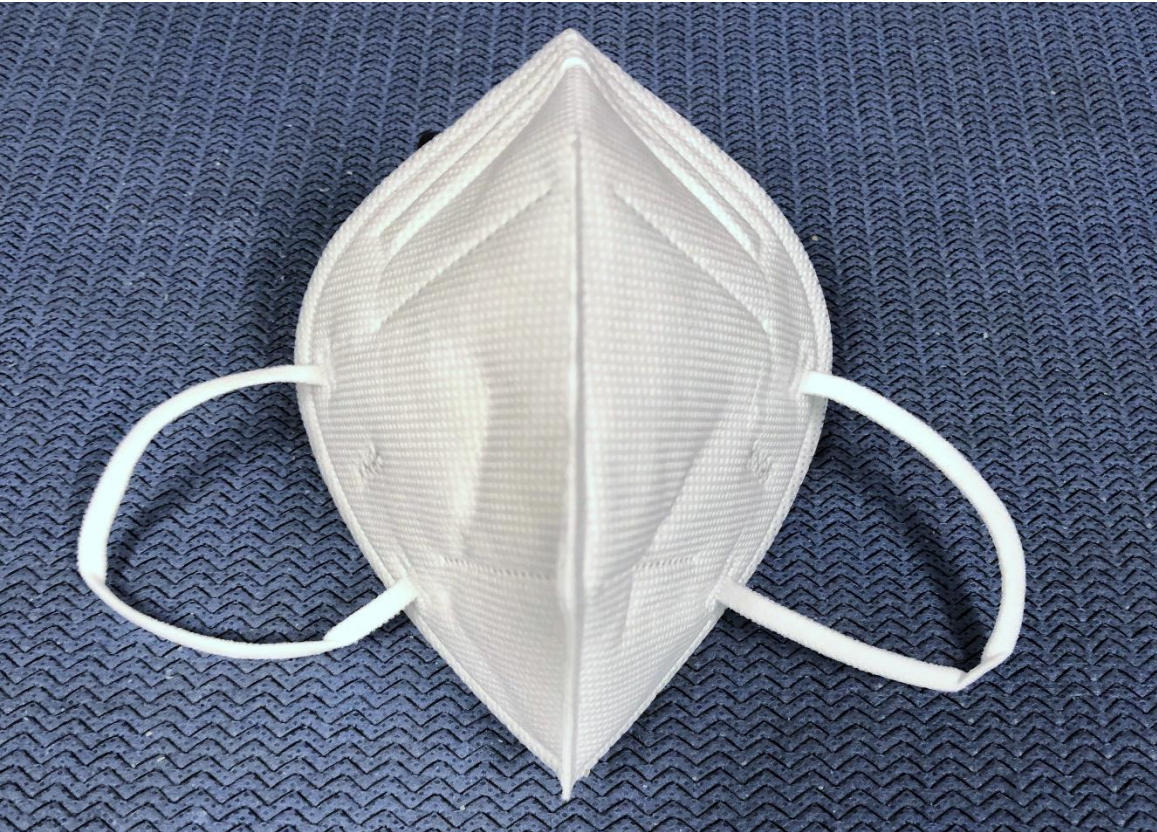
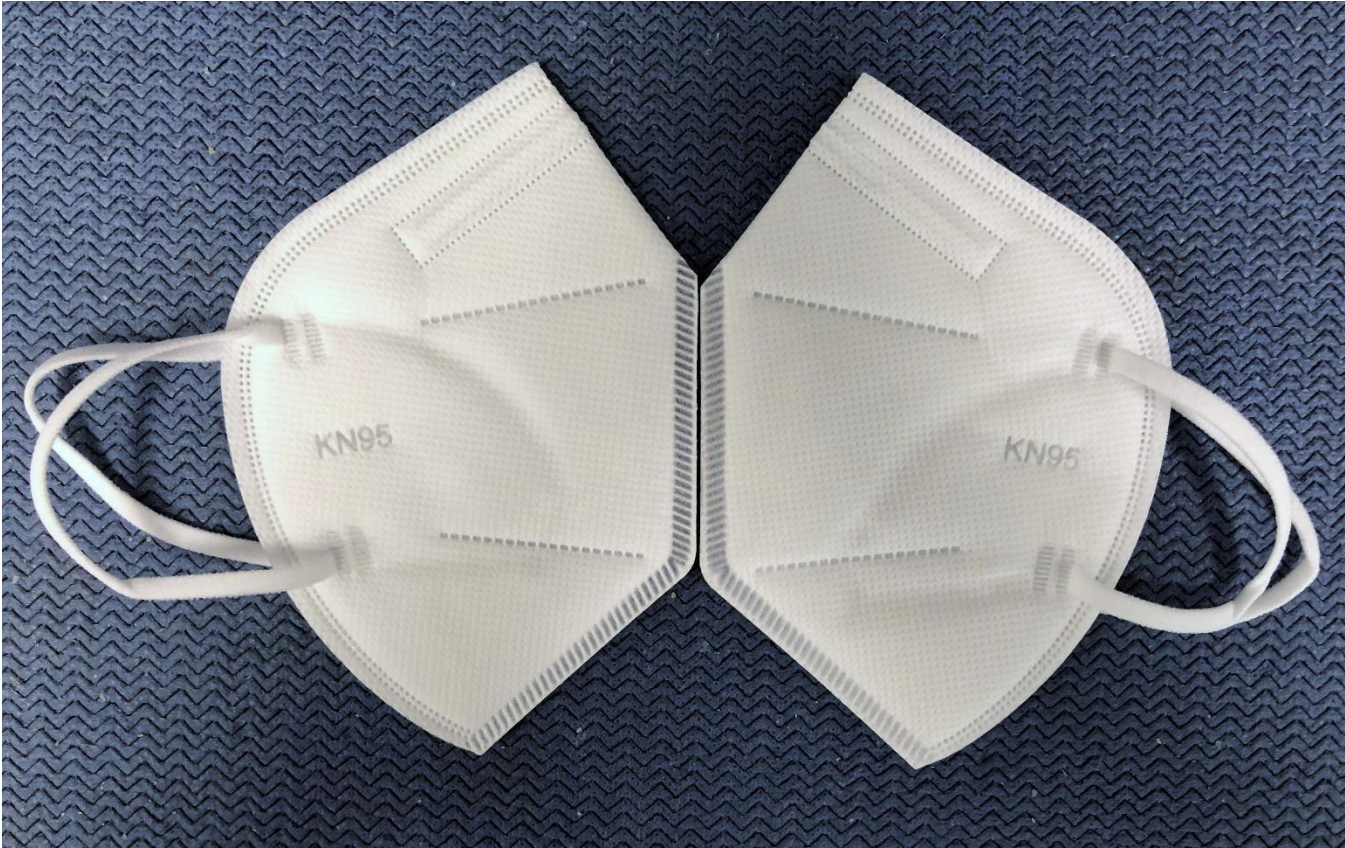
圣光医用制品股份有限公司

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