NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Scotics Science & Technology Co.
Model Tested: SKSS Sterile N95
Date Tested: April 14, 2020

These findings pertain to the Scotics Science & Technology Co., model SKSS Sterile N95. The labeling for these respirators indicate they meet GB19083-2010. This is the Chinese standard for Technical Requirements for Protective Face Mask for Medical Use.

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

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.

The maximum and minimum filter efficiency was 97.36% and 96.65%, 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. Therefore, even though the filter efficiency measured was more than 95%, users need to 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: April 14, 2020
Report Prepared: April 16, 2020
Manufacturer: Scotics Science & Technology Co.
Item Tested: SKSS Sterile N95
Country of Certification: China (Chinese Standard GB19083-2010)

<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>
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</table>

Minimum Filter Efficiency: 96.65  Maximum Filter Efficiency: 97.36

- 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.
型号：立体折叠型
数量：80片

- 产品性能符合GB 19083-2010标准要求
- 产品有效期二年
- 单包装破损，禁止使用，用后销毁。
- 避光、干燥、防热存放。
- 其他内容详见说明书

生产批号：052002003
生产日期：2020年2月20日
失效日期：2022年2月19日

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