

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Qingdao Miuton Medical Co., Ltd.

Model Tested: N95 Protective Mask

Date Tested: June 10, 2020

These findings pertain to the Qingdao Miuton Medical Co., Ltd., N95 Protective Mask. The packaging and labeling for this product indicate that it meets EN149:2001+A1:2009 (the European standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking).

Twenty 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 90.24% and 87.70%, respectively. All twenty respirators measured less 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 10, 2020

Report Prepared: June 10, 2020

Manufacturer: Qingdao Miuton Medical Co., Ltd.

Item Tested: N95 Protective Mask

Country of Certification: China (EN149:2001+A1:2009)

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	6.4	10.6	10.6	89.40
2	85	6.7	10.5	10.5	89.50
3	85	7.1	11.2	11.2	88.80
4	85	6.3	10.0	10.0	90.00
5	85	6.1	10.4	10.4	89.60
6	85	6.8	11.4	11.4	88.60
7	85	6.4	10.9	10.9	89.10
8	85	6.5	11.1	11.1	88.90
9	85	6.7	11.4	11.4	88.60
10	85	6.8	10.8	10.8	89.20
Minimum Filter Efficiency: 88.60			Maximum Filter Efficiency: 90.00		

- 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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Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
11	85	6.3	9.73	9.76	90.24
12	85	6.9	10.9	10.9	89.10
13	85	6.0	10.1	10.1	89.90
14	85	6.2	10.5	10.5	89.50
15	85	7.2	11.1	11.1	88.90
16	85	7.1	11.3	11.3	88.70
17	85	6.4	10.7	10.7	89.30
18	85	6.1	12.3	12.3	87.70
19	85	5.5	10.9	10.9	89.10
20	85	7.3	11.1	11.1	88.90
Minimum Filter Efficiency: 87.70			Maximum Filter Efficiency: 90.24		

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使用说明

【产品名称】N95防护口罩 【产品规格】耳戴式 【适用范围】过滤空气中的颗粒物。
 【主要结构和组成】N95防护口罩由面层、滤层、里层、鼻夹、口罩带组成，面层、里层为熔粘无纺布，滤层为熔喷无纺布，鼻夹为可弯折的可塑性塑料，口罩带由无纺布或橡胶等其他弹性材料制成。
 【推荐使用时间】不超过72小时
 【储存条件】产品应贮存在室温、干燥、通风环境良好的库房内。
 【注意事项，其他警示及提示性内容】
 1) 本品不适合在缺氧环境下使用，仅限日常防护。
 2) 使用前不得接触液体、火焰。 3) 使用过程中如有不适，请立即停止使用。
 【执行标准】EN 149:2001+A1:2009 【贮存期】3年

Operating Instruction

[Product Name] N95 Protective Mask [Product Specifications] Ear-worn
 [Scope of Application] Achieve a very efficient filtration of airborne particles.
 [Main Structure & Composition] N95 Protective Mask is composed of surface layer, filtering layer, inner layer, nasal splint, and mask bandage. The surface layer and the inner layer are made of non-stick non-woven fabric. The filtering layer is made of meltblown non-woven fabric. The nasal splint is made of bendable plastic. The mask bandage is made of elastic material such as non-woven fabric or rubber.
 [Recommended Life Time] No more than 72 hours
 [Storage] Stored in a warehouse with room temperature, dry and well ventilated environment.
 [Notes, Warnings & Tips]
 1) The product is not suitable for use in hypoxic environments, and is limited to daily protective use.
 2) Do not touch liquid or flame before using the product.
 3) Please stop using the product immediately if you have any discomfort during using
 [Standard] EN 149:2001+A1:2009 [Storage Life] 3 years

生产日期：
 生产批号：20200316
 有效期至：20230315

Made in China

高明药堂医疗股份有限公司

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