NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Xiamen Lixia Medical Technology Co., Ltd.
Model Tested: Lixia Medical Respirator
Date Tested: May 5, 2020

These findings pertain to the Xiamen Lixia Medical Technology Co., Ltd., Lixia Medical 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 99.96% and 99.31%, 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

NPPTL
National Personal Protective Technology Laboratory

Test: Modified TEB-APR-STP-0059

Date Tested: May 5, 2020

Report Prepared: May 5, 2020

Manufacturer: Xiamen Lixia Medical Technology Co., Ltd.

Item Tested: Lixia Medical 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_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	9.3	0.10	0.22	99.78
2	85	10.8	0.09	0.09	99.91
3	85	8.8	0.13	0.27	99.73
4	85	8.8	0.08	0.21	99.79
5	85	9.1	0.15	0.19	99.81
6	85	9.0	0.06	0.22	99.78
7	85	8.8	0.61	0.69	99.31
8	85	10.9	0.17	0.17	99.83
9	85	11.0	0.02	0.04	99.96
10	85	13.4	0.52	0.53	99.47
Minimum Filter Efficiency: 99.31			**Maximum Filter Efficiency: 99.96**		

- 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-2020-78.10
Open Here
丽厦®
医用防护口罩
Medical respirator
【产品名称】医用防护口罩
【型号】N95
【规格】大号
【生产许可证编号】闽食药监械生产许20130354号
【注册证编号】闽械注准20182640005
【产品技术要求编号】闽械注准20182640005
【产品性能】符合闽械注准20182640005产品技术要求
【结构及组成】该产品由卫生用薄型非织造布（无纺布）制成，产品应无菌。
【产品适用范围】该产品可过滤空气中的颗粒物，阻隔飞沫、血液、体液、分泌物，供医务人员在医疗工作环境下的防护用。
【禁忌症】无
【使用方法】
1.取出口罩，鼻夹条在上边；
2.将口罩开口部分遮住口鼻和下颌，口罩带套在耳后，用双手的中指将鼻梁条由中间向内按压；
3.适当调整口罩位置，使得佩戴舒适。
【注意事项，警示以及提示性内容】
1. 该产品属于一次性使用，不得重复使用；使用前请检查包装情况，若包装破损应禁止使用。
2. 若使用中有头晕，过敏或其它不适症状产生，请停止使用。
3. 孕妇请参考医生建议使用。
4. 产品超过失效日期禁止使用。
【贮存】应贮存在相对湿度不超过85%，无腐蚀性气体和通风良好的室内；
【运输】应避免日晒、雨淋和机械损伤；
【生产批号】见包装标示处；
【生产日期】见包装标示处；
【失效日期】见包装标示处；
【使用期限】三年
6 923009 400067
【生产企业】厦门丽厦医疗科技有限公司
【注册人名称】厦门丽厦医疗科技有限公司
【生产地址】厦门市海沧区东孚大道2875号一号厂房四层南侧
【注册人住所】厦门市海沧区东孚大道2875号一号厂房四层南侧
【联系方式】400 860 4066 0592-8842666
【售后服务单位】厦门丽厦医疗科技有限公司
【图示说明】
STERILE EO
经环氧乙烷灭菌
STERILE
无菌
不得二次使用
【说明书修订日期】2019年08月08日
【说明书版本】01次

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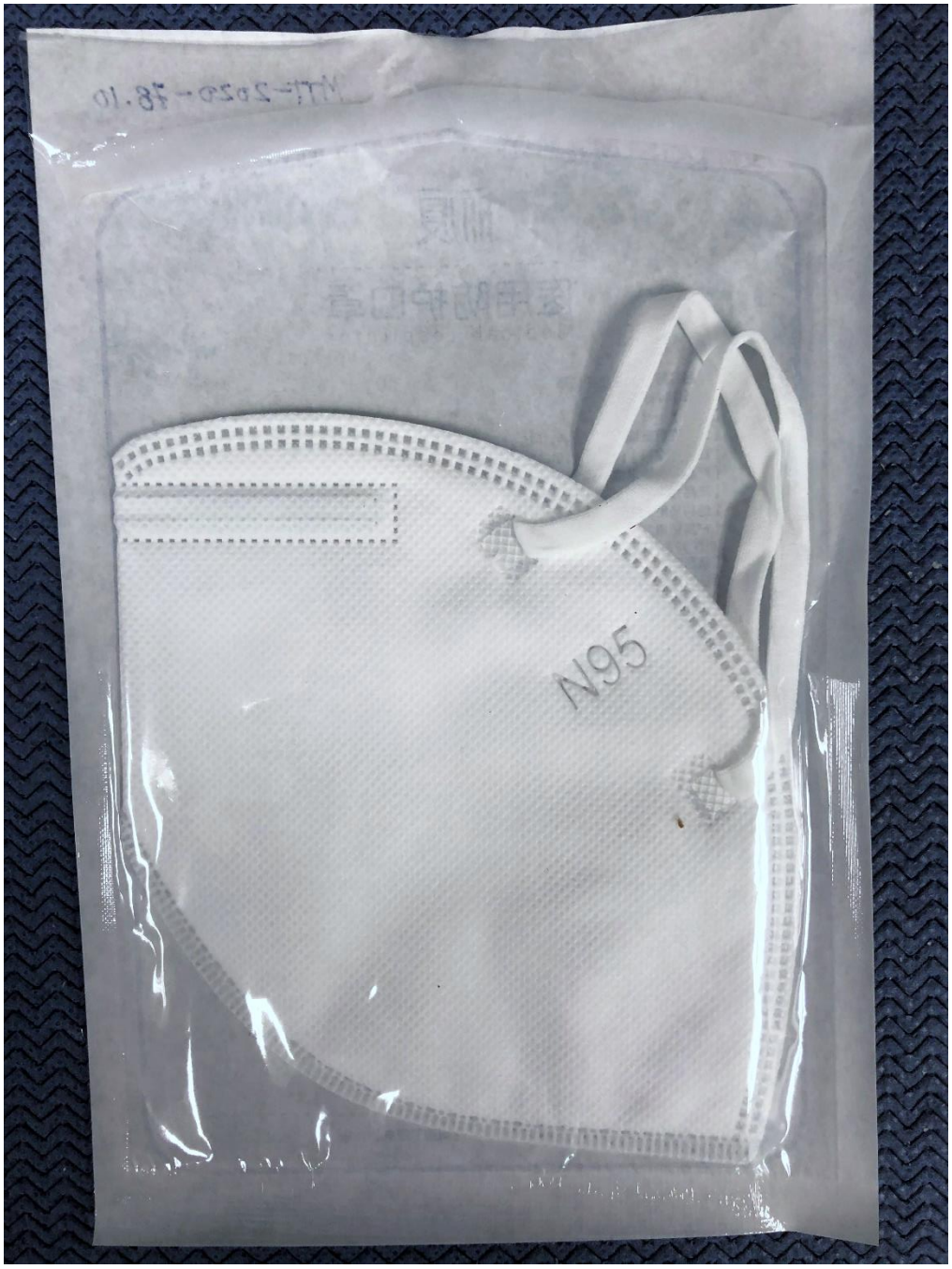


N95
N95

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