NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shandong Zhushi Pharmaceutical Group Co., Ltd.
Model Tested: Medical Protective Mask
Date Tested: June 1, 2020

These findings pertain to the Shandong Zhushi Pharmaceutical Group 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 99.10% and 98.48%, 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: June 1, 2020

Report Prepared: June 1, 2020

Manufacturer: Shandong Zhushi Pharmaceutical Group 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_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	16.5	1.28	1.28	98.72
2	85	18.9	1.10	1.10	98.90
3	85	20.8	1.52	1.52	98.48
4	85	13.9	1.15	1.15	98.85
5	85	15.0	0.90	0.90	99.10
6	85	18.1	1.01	1.01	98.99
7	85	14.3	0.94	0.94	99.06
8	85	14.3	1.18	1.18	98.82
9	85	16.1	0.95	0.95	99.05
10	85	14.1	0.96	0.96	99.04
Minimum Filter Efficiency: 98.48			**Maximum Filter Efficiency: 99.10**		

- 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-2020-217
【执行标准号】GB19083-2010
【注册证编号】鲁械注准20202140312
【产品技术要求编号】鲁械注准20202140312
【生产许可证编号】鲁食药监械生产许20140053号
东贝
MEDICAL
PROTECTIVE MASK
医用防护口罩
KN95
1片/袋
【适用范围】
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、分泌物等用,不能
用于隔离重症监护病区房等有严格微生物
指标控制要求的场所。
山东朱氏药业集团有限公司
Shandong Zhushi Pharmaceutical Group Co., Ltd

医用防护口罩

东贝

【产品名称】医用防护口罩
【型号规格】非无菌折叠型
【产品结构组成】本产品由口罩体，鼻夹和口罩带组成。口罩体最外层和最里层为无纺布，夹层为熔喷无纺布；口罩带为涤纶松紧带；鼻夹为金属铝条制成；产品以非无菌形式提供。
【产品性能指标】1.鼻夹应具有可调节性；
2.细菌菌落总数≤200CFU/G;真菌菌落总数≤100CFU/G；
3.非油性颗粒过滤效率≥95%。
【灭菌要求】非无菌。
【适用范围】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、分泌物等用,不能用于隔离重症监护病区房等有严格微生物指标控制要求的场所。
【禁 忌 症】对无纺布材料过敏者禁止使用。
【使用说明】1.打开口罩用手扶住口罩固定在面部，使鼻夹位于口罩上方；
2.口罩带戴与头部；
3.调整鼻夹至鼻梁形状，使口罩紧贴面部，如不合适请更换其他规格口罩，禁止头发进入面罩封边内，以防止密合性不合格；
4.产品使用4小时后请更换新的产品；
5.一次性使用，用后销毁。
【注意事项、警示以及提示的内容】
1.如使用时出现头晕、恶心、呼吸困难等情况请速离开感染区域并更换本产品；
2.产品用后请销毁，禁止重复使用；
3.在产品使用前检查口罩的适合性，如不合适请进行更换，如果有头发进入面罩封边内，以防止密合性不合格；
4.本品为一次性使用，使用前请仔细检查包装袋，如有破损严禁使用；
5.使用本产品前应认真阅读说明书，并查看封口处生产批号/生产日期，逾期不得使用；
6.产品开封后应尽快使用的提示。

【标签、包装标识样图】

仅限一次性使用　　包装破损 禁止使用

【运输及储存条件】本产品贮藏在无腐蚀性气体、干燥、避免日晒、通风条件良好、清洁的环境内；运输及搬运时应注意小心轻放。
【执行标准号】GB19083-2010
【注册证编号】鲁械注准20202140312
【产品技术要求编号】鲁械注准20202140312
【生产许可证编号】鲁食药监械生产许20140053号
【注册人】山东朱氏药业集团有限公司
【住　　所】单县经济技术开发区樊楼路南
【联系方式】0530-4265777
【售后服务单位】山东朱氏药业集团有限公司
【生产企业】山东朱氏药业集团有限公司
【生产地址】山东单县经济技术开发区和
山东单县经济技术开发区食品药品产业园单德路6号
【联系方式】0530-4265777
【生产日期】见包装
【有效期】12个月

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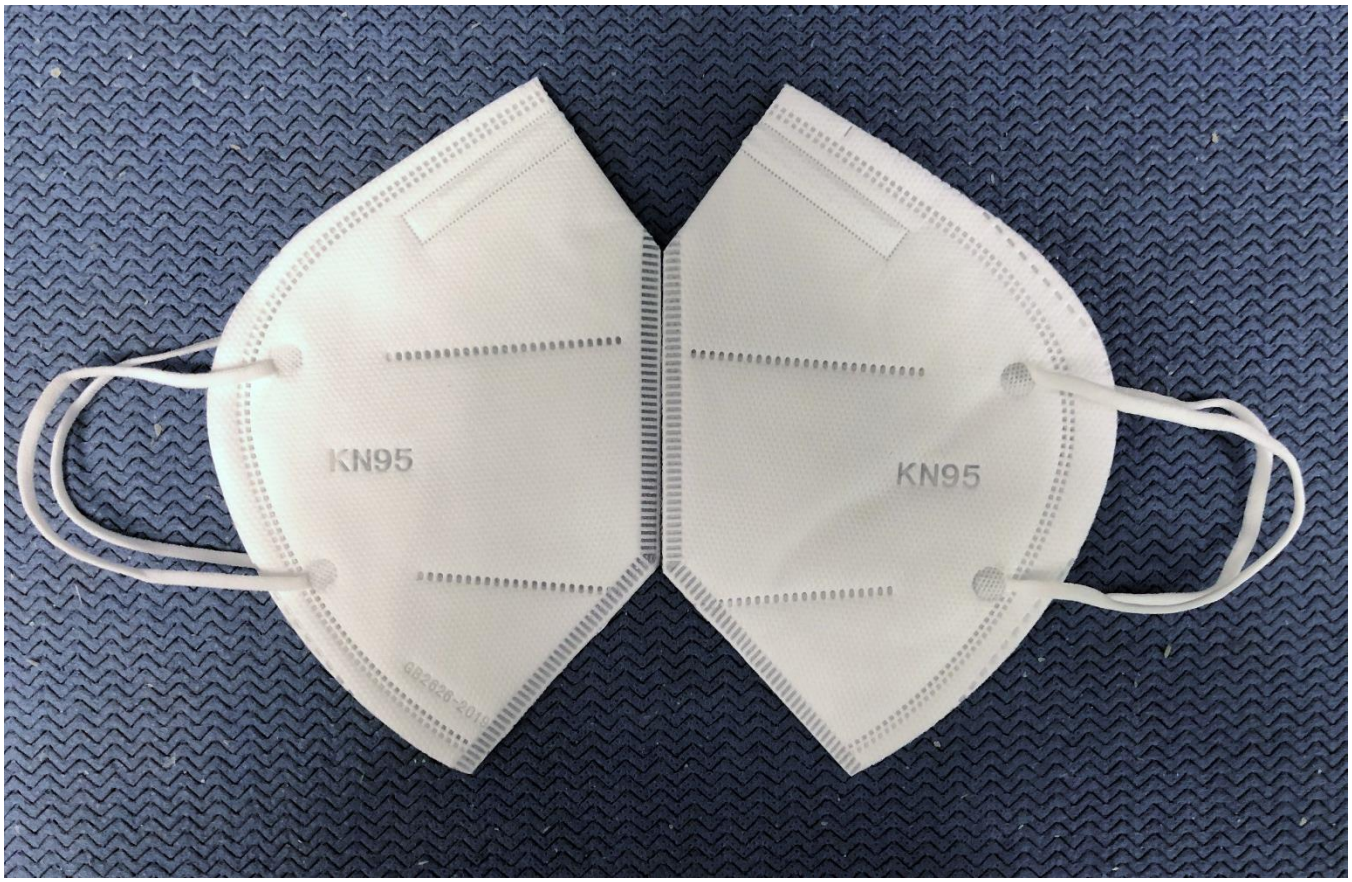

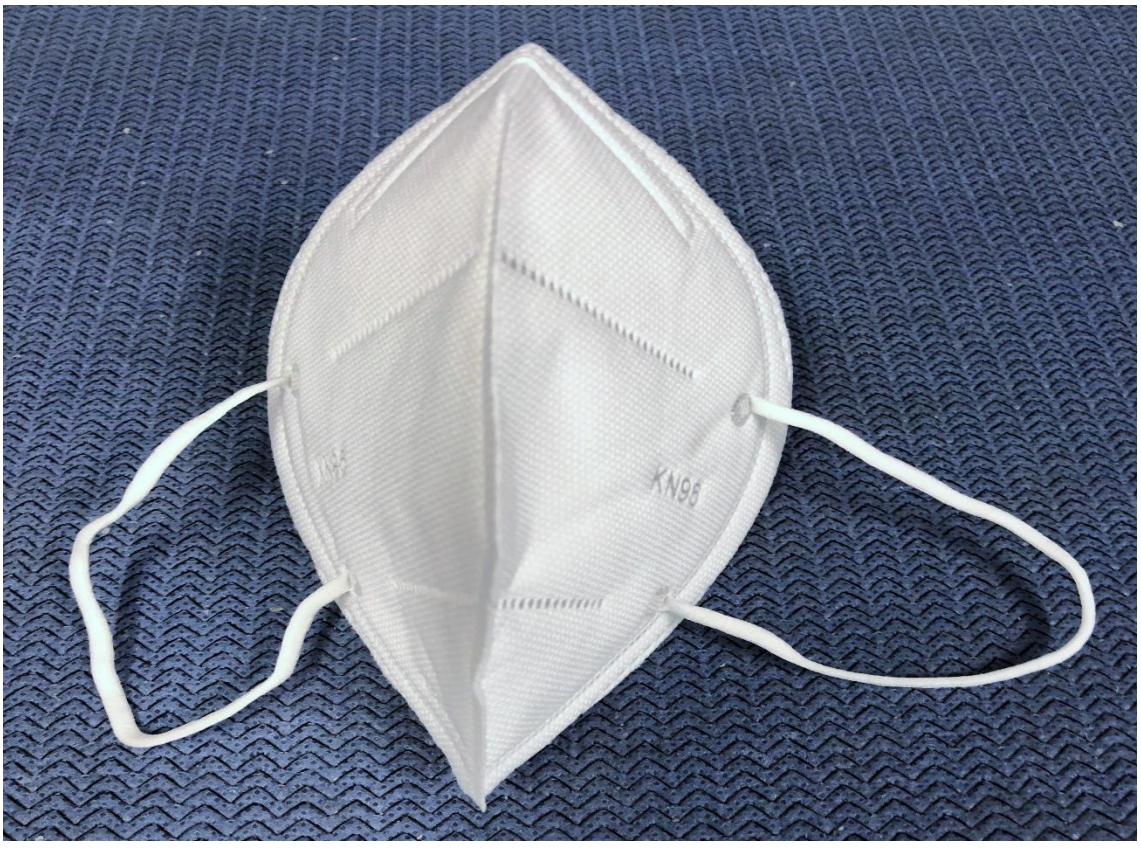

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