NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Baoji Taidakang Medical Technology Co., Ltd
Model Tested: Folding Mask with Ear Loop
Date Tested: May 13, 2020

These findings pertain to the Baoji Taidakang Medical Technology Co., Ltd., Folding Mask with Ear Loop. The labeling for these respirators indicate 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 99.51% and 99.25%, 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 13, 2020

Report Prepared: May 13, 2020

Manufacturer: Baoji Taidakang Medical Technology Co., Ltd

Item Tested: Folding Mask with Ear Loop

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	12.8	0.51	0.51	99.49
2	85	13.8	0.49	0.49	99.51
3	85	12.8	0.64	0.64	99.36
4	85	13.2	0.59	0.59	99.41
5	85	14.5	0.55	0.55	99.45
6	85	13.6	0.61	0.61	99.39
7	85	14.3	0.68	0.68	99.32
8	85	13.5	0.73	0.73	99.27
9	85	14.2	0.60	0.60	99.40
10	85	13.9	0.75	0.75	99.25
Minimum Filter Efficiency: 99.25			**Maximum Filter Efficiency: 99.51**		

- 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-2020-47.2 95-2
泰达康™
TAI DA KANG
医用防护口罩
Protective Face Mask For Medical Use
过滤等级 1级 过滤效率≥95%
STERILE 无菌
STERILE EO 环氧乙烷灭菌
执行标准号 GB 19083-2010
生产许可证编号 陕药监械生产许20200014号
注册证编号/产品技术要求编号 陕械注准20202140026
产品使用说明
适用范围 适用于戴在医疗机构与病毒物料接触的人员面部，用于防止来自患者的病毒向医务人员传播。
产品结构组成 产品由口罩体、鼻夹及口罩带组成。本品由外层PP无纺布，中间层PP熔喷布，过滤层PP熔喷布，内层PP无纺布四层组成。产品经环氧乙烷灭菌,以无菌形式提供。
使用方法
1）将口罩打开，面向口罩无鼻夹的一面，使鼻夹位于口罩上方；
2）双手分别拉住两侧耳带，用口罩抵住下巴；
3）将耳带挂于耳后，调整耳带至尽可能感觉舒适；
4）将双手手指置于金属鼻夹中部，一边向内按压一边顺着鼻夹向两侧移动指尖，直至将鼻夹完全按压成鼻梁形状为止。仅用单手捏口罩鼻夹可能会影响口罩的密合性；
5）在进入工作区域之前，必须检查口罩与脸部的密合性。
禁忌症 无
注意事项、警示以及提示的内容
1）不适用于防护有害气体和蒸气的呼吸防护用品。不适用于缺氧环境、水下作业、逃生和消防用呼吸防护用品。如气体的蒸气、油性气溶液、石棉、砷、镉、铅等浓度超过10倍允许暴露限值或职业接触限值（PEL/OEL）等。本防护口罩不产生氧气。
2）使用前请检查包装是否完好，对外包装标志、生产日期、有效期进行确认，并在灭菌有效期内使用。
3）应确保口罩展开后覆盖住鼻梁至下颌处，以获得预期的防护效果。
4）本产品为一次性用品，禁止重复使用。
5）本产品已采用环氧乙烷灭菌，使用前若发现包装破损，严禁使用。
6）对无纺布过敏者慎用。
7）如果口罩破损、脏污或呼吸阻力变大时，请离开污染区域并更换防护口罩。
8）产品使用后，应按医院和环保部门要求进行处理。
贮存条件 应贮存在常温、通风、相对湿度不高于75%、无腐蚀性气体的环境中，远离火源及易燃物。
生产日期/生产批号 见包装
灭菌有效期 二年
注册人/生产企业名称/售后服务单位 宝鸡泰达康医疗科技有限公司
注册人/生产企业住所/生产企业地址 陕西省宝鸡市高新开发区天王镇陕西泰华物流产业有限公司院内2号厂房
电话 0917-6786999 / 6782999 邮编 721305
E-mail taidakang@163.com
使用前请参见使用说明
一次性使用
6 973165 290002
1 只/袋 折叠形耳挂式 15.5cm × 10cm


泰达康
TAI DA KANG
医用防护口罩
符合国标 GB 19083-2010

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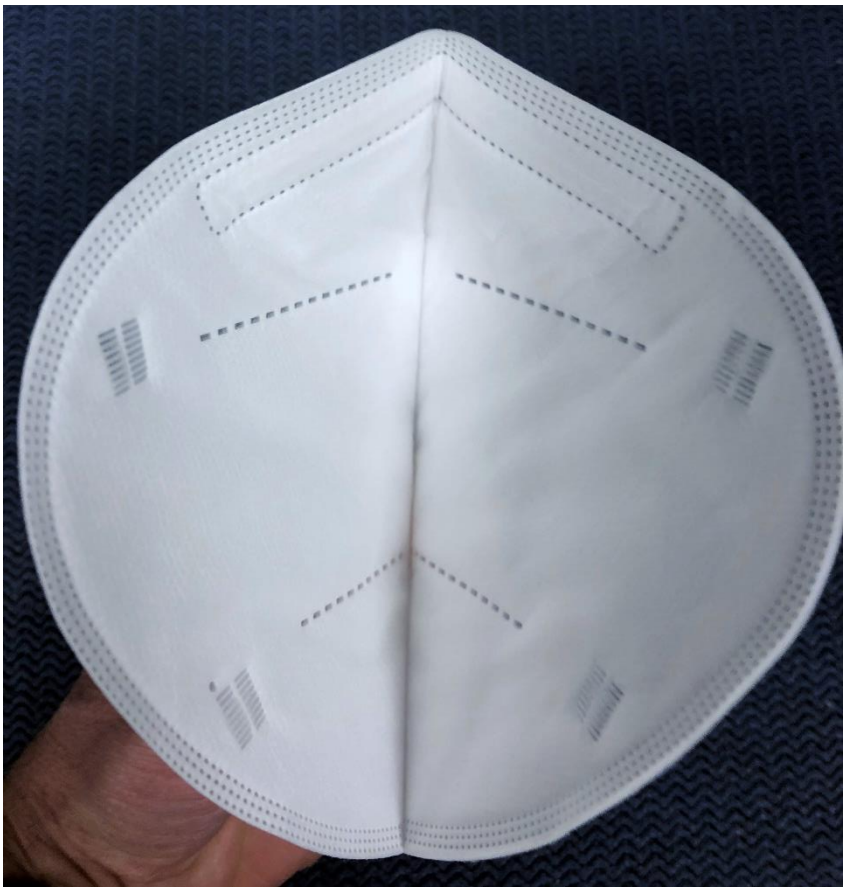


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