NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shengguang Medical Products Co., Ltd.
Model Tested: Duckbill Shape Wearing by Ear
Date Tested: May 22, 2020

These findings pertain to the Shengguang Medical Products Co., Ltd., Duckbill Shape Wearing by Ear. 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 99.97% and 99.45%, 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 22, 2020

Report Prepared: May 26, 2020

Manufacturer: Shengguang Medical Products Co., Ltd.

Item Tested: Duckbill Shape Wearing by Ear

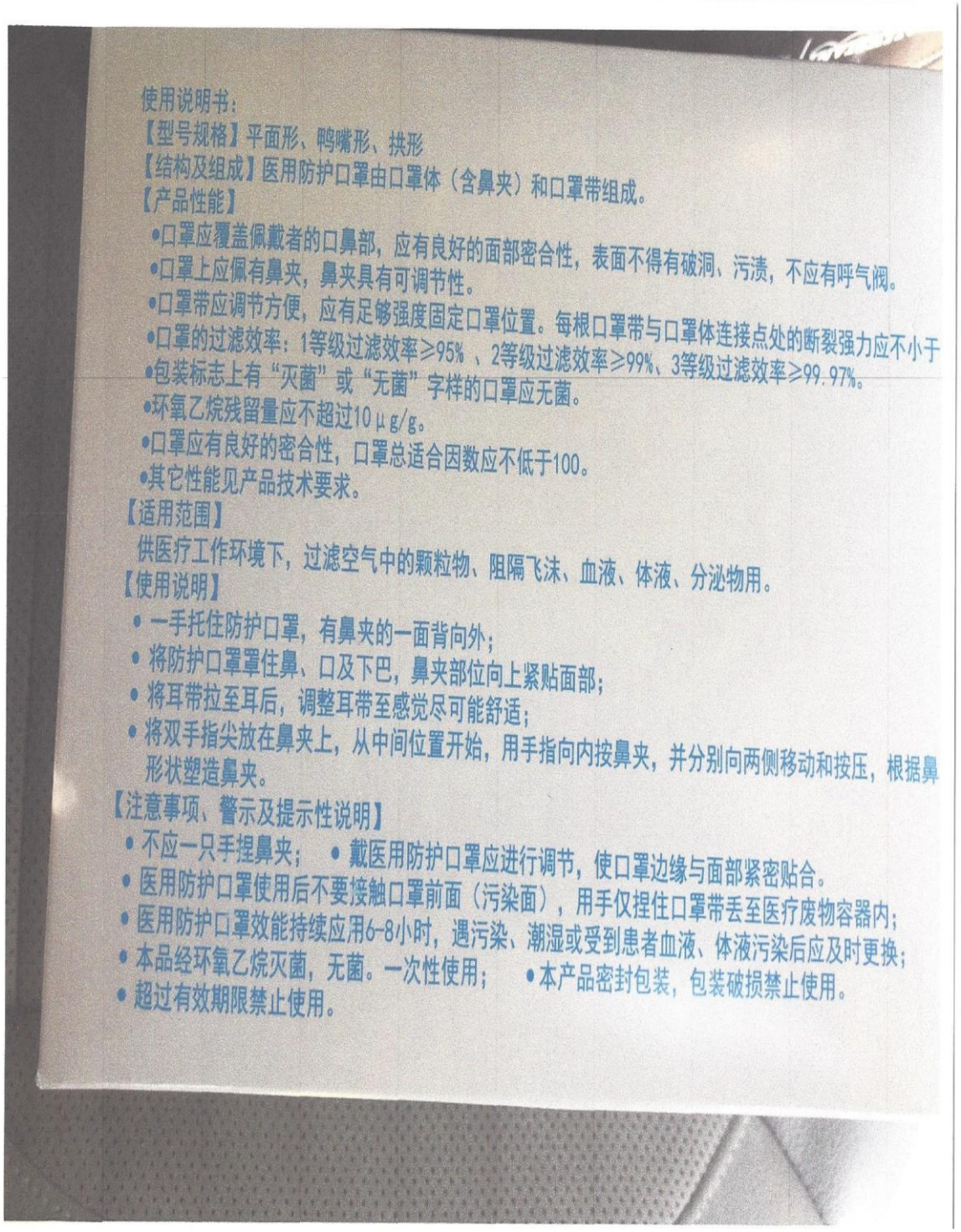
Country of Certification: China (GB19083-2010)

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	22.3	0.55	0.55	99.45
2	85	22.9	0.52	0.52	99.48
3	85	24.5	0.00	0.03	99.97
4	85	38.2	0.06	0.06	99.94
5	85	22.5	0.53	0.53	99.47
6	85	24.0	0.40	0.40	99.60
7	85	35.8	0.31	0.31	99.69
8	85	29.2	0.49	0.49	99.51
9	85	22.8	0.35	0.35	99.65
10	85	21.9	0.00	0.05	99.95
Minimum Filter Efficiency: 99.45			**Maximum Filter Efficiency: 99.97**		

- 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.


ShengGuang
圣光 ®
生产许可证编号：豫食药监械生产许20160010号
注册证编号：豫械注准20182140825
产品技术要求编号：豫械注准20182140825
本企业通过ISO 9001、ISO 13485质量体系认证
本产品符合GB19083-2010标准要求
医用防护口罩
过滤效率等级:1级
(过滤效率≥95%)
STERILE EO
STERILE
圣光医用制品股份有限公司



使用说明书：

【型号规格】平面形、鸭嘴形、拱形

【结构及组成】医用防护口罩由口罩体（含鼻夹）和口罩带组成。

【产品性能】

- 口罩应覆盖佩戴者的口鼻部，应有良好的面部密合性，表面不得有破洞、污渍，不应有呼气阀。
- 口罩上应佩有鼻夹，鼻夹具有可调节性。
- 口罩带应调节方便，应有足够强度固定口罩位置。每根口罩带与口罩体连接点处的断裂强力应不小于
- 口罩的过滤效率：1等级过滤效率≥95%、2等级过滤效率≥99%、3等级过滤效率≥99.97%。
- 包装标志上有“灭菌”或“无菌”字样的口罩应无菌。
- 环氧乙烷残留量应不超过10μg/g。
- 口罩应有良好的密合性，口罩总适合因数应不低于100。
- 其它性能见产品技术要求。

【适用范围】

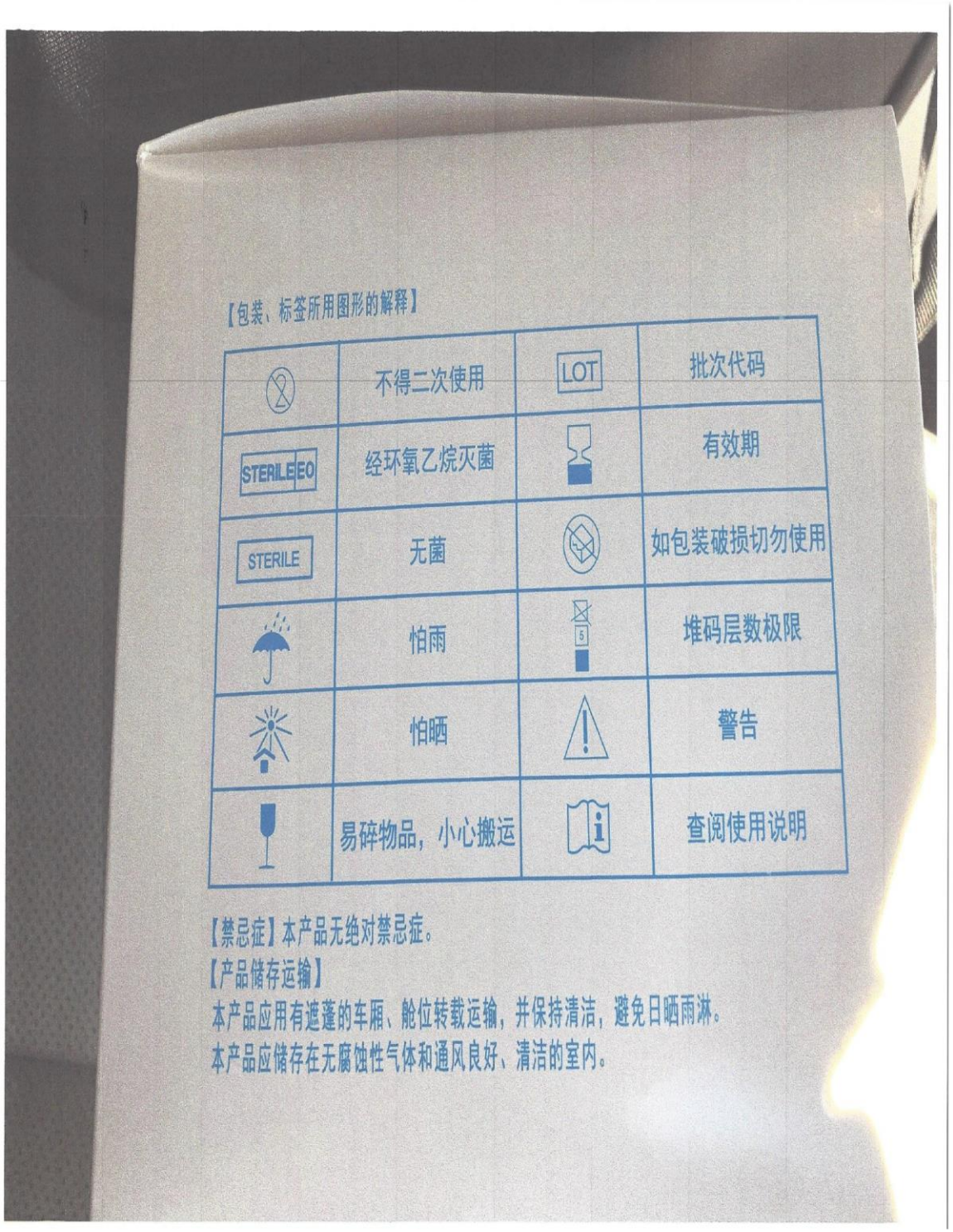
供医疗工作环境下，过滤空气中的颗粒物、阻隔飞沫、血液、体液、分泌物用。

【使用说明】

- 一手托住防护口罩，有鼻夹的一面背向外；
- 将防护口罩罩住鼻、口及下巴，鼻夹部位向上紧贴面部；
- 将耳带拉至耳后，调整耳带至感觉尽可能舒适；
- 将双手指尖放在鼻夹上，从中间位置开始，用手指向内按鼻夹，并分别向两侧移动和按压，根据鼻形状塑造鼻夹。

【注意事项、警示及提示性说明】

- 不应一只手捏鼻夹；
- 戴医用防护口罩应进行调节，使口罩边缘与面部紧密贴合。
- 医用防护口罩使用后不要接触口罩前面（污染面），用手仅捏住口罩带丢至医疗废物容器内；
- 医用防护口罩效能持续应用6-8小时，遇污染、潮湿或受到患者血液、体液污染后应及时更换；
- 本品经环氧乙烷灭菌，无菌。一次性使用；
- 本产品密封包装，包装破损禁止使用。
- 超过有效期限禁止使用。



【包装、标签所用图形的解释】

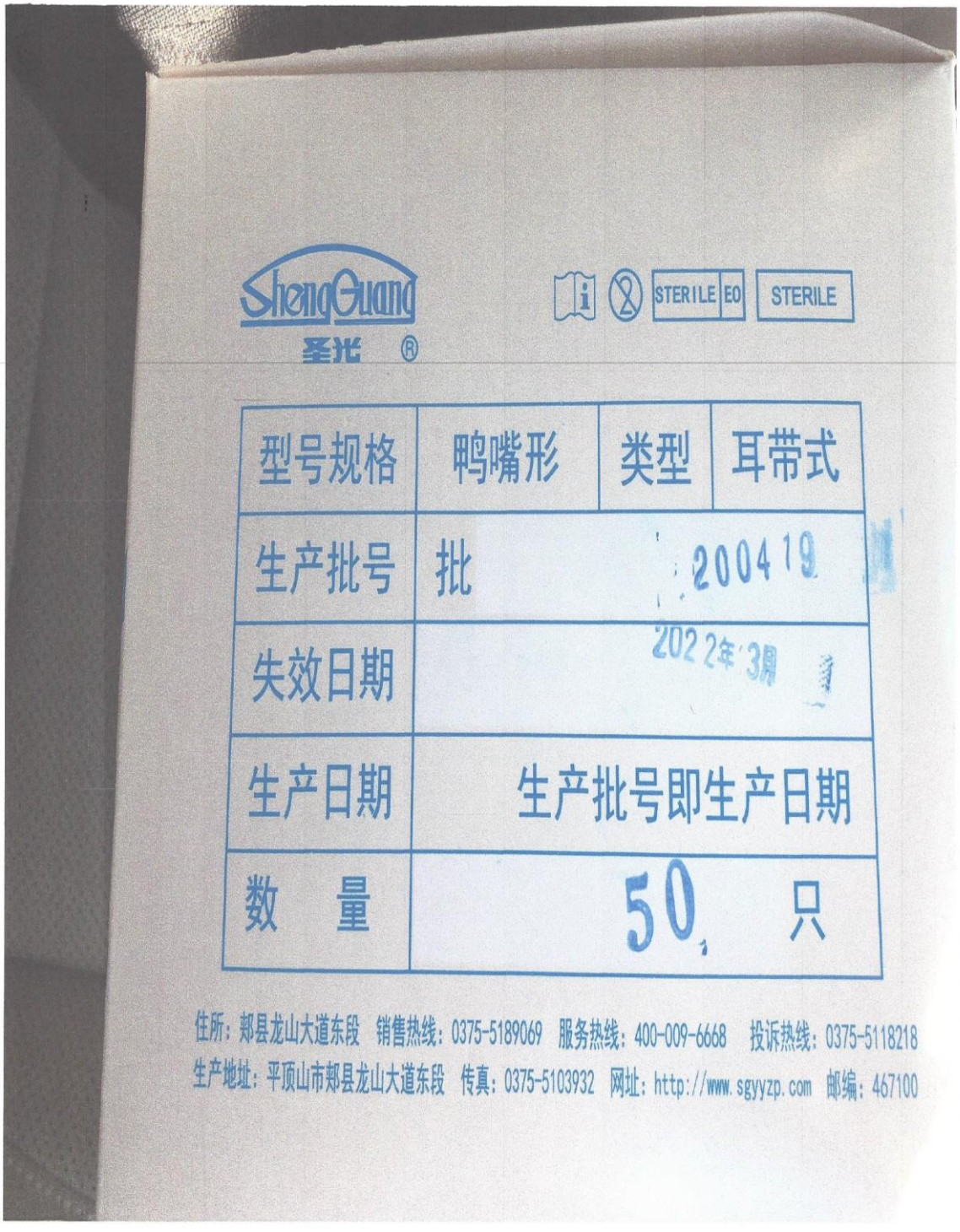
	不得二次使用	LOT	批次代码
STERILE EO	经环氧乙烷灭菌		有效期
STERILE	无菌		如包装破损切勿使用
	怕雨	5	堆码层数极限
	怕晒		警告
	易碎物品，小心搬运		查阅使用说明

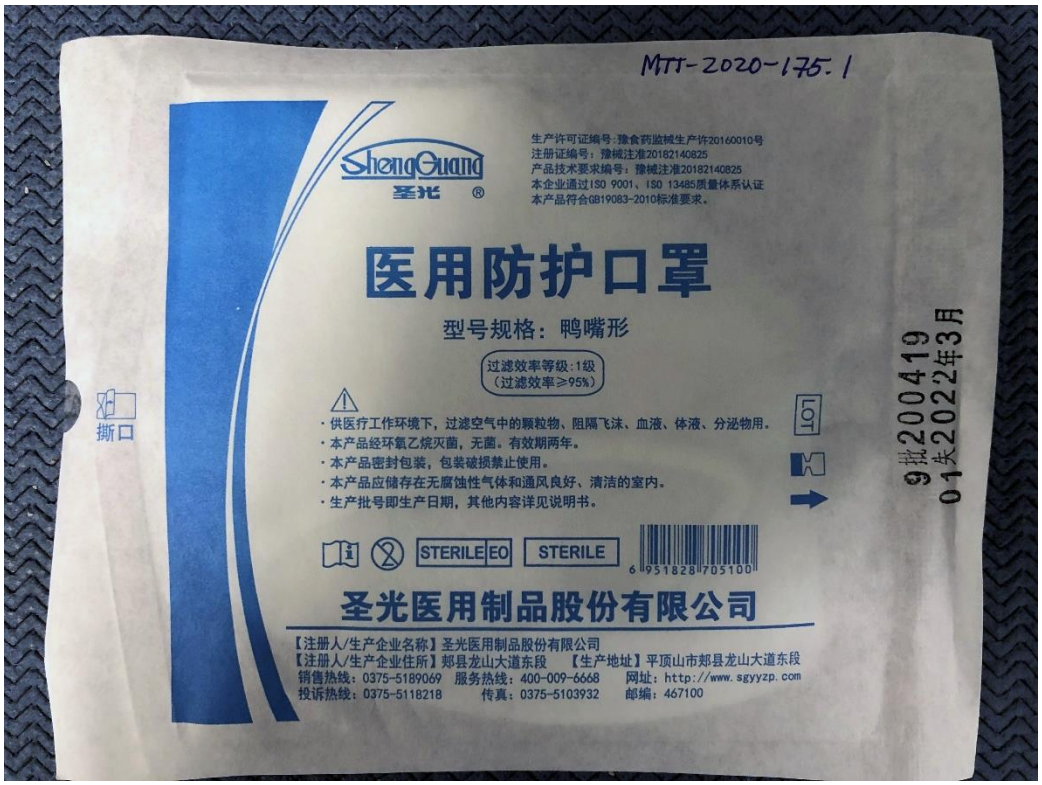
【禁忌症】本产品无绝对禁忌症。

【产品储存运输】

本产品应用有遮蓬的车厢、舱位转载运输，并保持清洁，避免日晒雨淋。

本产品应储存在无腐蚀性气体和通风良好、清洁的室内。


ShengGuang
圣光 ®
STERILE EO
STERILE
型号规格
鸭嘴形
类型
耳带式
生产批号
批
200419
失效日期
2022年3月
生产日期
生产批号即生产日期
数 量
50 只
住所：郏县龙山大道东段 销售热线：0375-5189069 服务热线：400-009-6668 投诉热线：0375-5118218
生产地址：平顶山市郏县龙山大道东段 传真：0375-5103932 网址：http://www.sgyyzp.com 邮编：467100


MTT-2020-175.1
ShengGuang
圣光 ®
生产许可证编号：豫食药监械生产许20160010号
注册证编号：豫械注准20182140825
产品技术要求编号：豫械注准20182140825
本企业通过ISO 9001、ISO 13485质量体系认证
本产品符合GB19083-2010标准要求。
医用防护口罩
型号规格：鸭嘴形
过滤效率等级:1级
（过滤效率≥95%）
撕口
·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、分泌物用。
·本产品经环氧乙烷灭菌，无菌。有效期两年。
·本产品密封包装，包装破损禁止使用。
·本产品应储存在无腐蚀性气体和通风良好、清洁的室内。
·生产批号即生产日期，其他内容详见说明书。
LOT
STERILE EO
STERILE
6 951828 705100
9批200419
01失2022年3月
圣光医用制品股份有限公司
【注册人/生产企业名称】圣光医用制品股份有限公司
【注册人/生产企业住所】郏县龙山大道东段 【生产地址】平顶山市郏县龙山大道东段
销售热线：0375-5189069 服务热线：400-009-6668 网址：http://www.sgyyzp.com
投诉热线：0375-5118218 传真：0375-5103932 邮编：467100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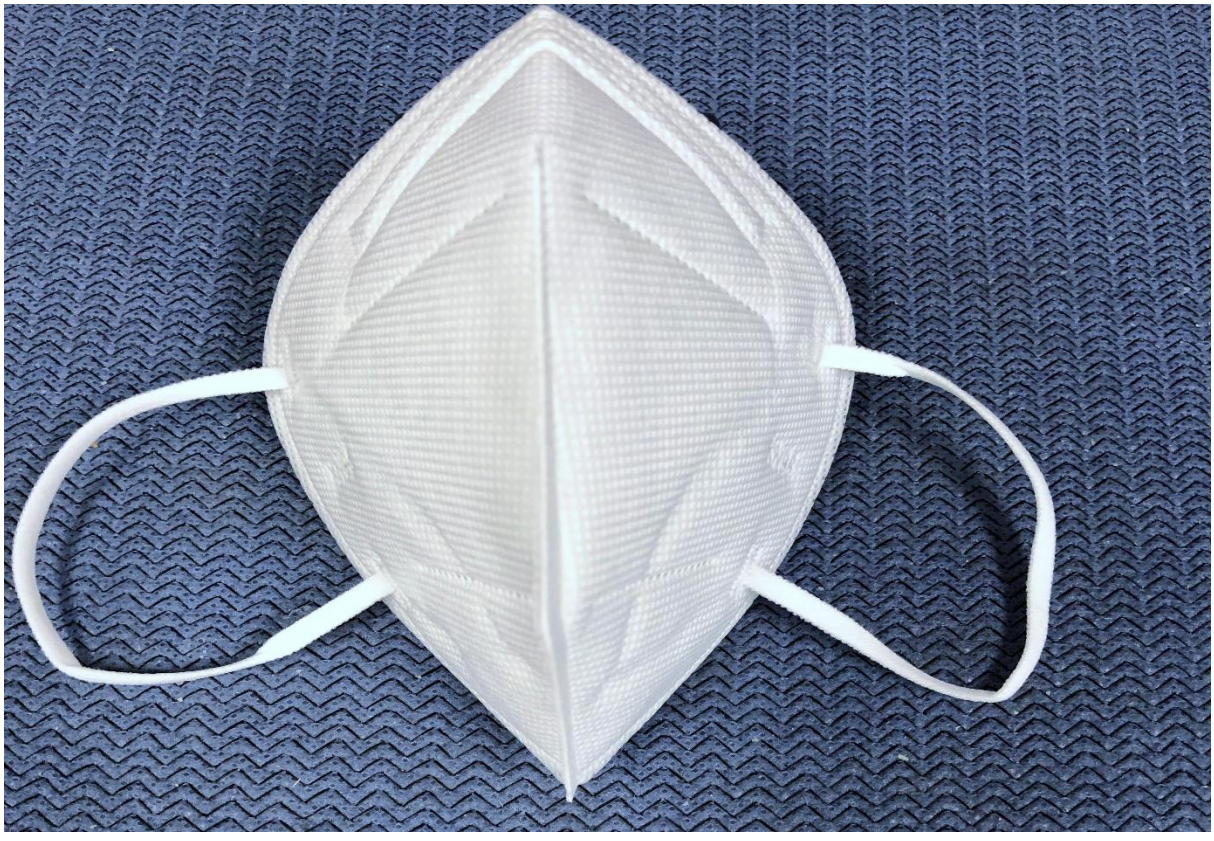


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