

NPPTL COVID-19 Response: Beyond Shelf Life/Stockpiled Respirator Assessment

Manufacturer: Shanghai Gangkai Purifying Products Co., Ltd.

Model Tested: GIKO 1200

Date Tested: June 9, 2020

Report Prepared: June 9, 2020

These findings pertain to the Shanghai Gangkai Purifying Products Co., Ltd., GIKO 1200 (TC-84A-4006) submitted for testing, and may not be applicable to other stockpile facilities and/or under different environmental storage conditions. The maximum and minimum filter efficiency was 97.04% and 84.00%, respectively. Eighteen respirators measured more than 95% efficiency. Two respirators measured less than 95% efficiency. There was no designated expiration date.

NIOSH regulation sets the minimum quality and performance requirements for the approval of respirators (42 CFR 84). **NIOSH does not have requirements for shelf life or storage conditions for particulate-only APRs.** The approval holder (i.e. the entity that is granted the approval from NIOSH) is responsible for understanding how their products' design or performance may be affected by various use or storage conditions and must provide instruction for establishing the proper use, storage, and maintenance procedures for their approved products, which may include designating a shelf life. FFR or particulate filter packaging (such as the box) often includes NIOSH-approved user instructions, label information, and recommendations on shelf life. Additionally, some approval holders also disseminate recommendations related to storage and shelf life through resources such as user and web notices. The respirators tested in this study were generally not designed for long-term storage.

Based on research conducted by NIOSH and this limited testing, NIOSH does not have enough information to definitively know the level of protection that may be provided by respirators that 1) are stored for prolonged periods of times; 2) are stored under various storage conditions; or 3) have exceeded the approval holder's designated shelf life. Users of respirators that have exceeded the designated shelf life should be forewarned to avoid a false sense of confidence; these devices may not provide the same level of protection as those that have not exceeded the designated shelf life. We recommend contacting the approval holder(s) of the respirators in the stockpile with specific questions regarding the use of product beyond the manufacturer- designated shelf life.

The results provided in this letter are specific to the subset of NIOSH-approved N95s, past their designated shelf life, that were provided to NPPTL for evaluation.

These results will be added to the CDC guidance for [Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life](#).



Evaluation of Stockpiled and Beyond Manufacturer-Designated Shelf Life N95s

Test: TEB-APR-STP-0059

Manufacturer: Shanghai Gangkai Purifying Products Co., Ltd.

Item Tested: GIKO 1200

Expiration Date: None Provided

Manufacture Date: None Provided

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	10.0	3.91	3.91	96.09
2	85	10.6	3.73	3.76	96.24
3	85	10.4	4.78	4.78	95.22
4	85	11.3	2.96	2.96	97.04
5	85	10.5	3.68	3.68	96.32
6	85	11.6	3.10	3.10	96.90
7	85	10.9	4.00	4.00	96.00
8	85	10.4	4.28	4.28	95.72
9	85	9.6	15.2	16.0	84.00
10	85	11.4	3.39	3.39	96.61
11	85	9.9	5.41	5.41	94.59
12	85	10.5	3.84	3.84	96.16
13	85	10.9	3.86	3.86	96.14
14	85	10.6	4.52	4.52	95.48
15	85	10.3	3.65	3.65	96.35
16	85	10.7	4.58	4.58	95.42
17	85	10.4	3.67	3.67	96.33
18	85	9.6	4.05	4.05	95.95
19	85	11.4	3.78	3.78	96.22
20	85	10.9	4.01	4.01	95.99
Minimum Filter Efficiency: 84.00			Maximum Filter Efficiency: 97.04		

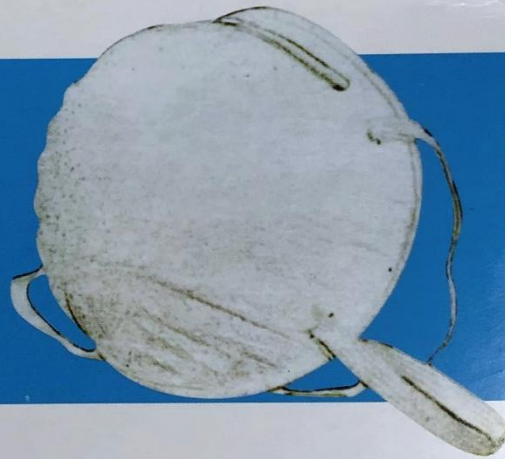
MTT-2020-239.2



符合中国LD29-92标准

N95 高级过滤口罩
Particulate Respirator N95

1200



保质期：二年



Qty: **20** pcs

**NIOSH Approved
Respirator**
美国职业安全与健康
研究所认证口罩

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FILTERING FACEPIECE APPROVAL LABEL



Shanghai Gangkai Purifying Products Co., Ltd.
201600 Shanghai PR China
0086-21-57775401

THIS RESPIRATOR IS APPROVES ONLY IN THE FOLLOWING CONFIGURATION

TC	Protection ¹	Respirator	Cautions and Limitations ²
		GIKO 1200	
84A-4006	N95	X	ABCJMNO

1. Protection

N95-Particulate Filter (95% filter efficiency level)
effective against particulate aerosols free of oil
time use restrictions may apply

2. Cautions and Limitations

- A- Not for use in atmospheres containing less than 19.5% oxygen.
- B. Not for use in atmospheres immediately dangerous to life or health.
- C- Do not exceed maximum use concentrations established by regulatory standards
- J- Failure to properly use and maintain this product could result in injury or death.
- M- All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA and other applicable regulations.
- N- Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O- Refer to users instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P- NIOSH does not evaluate for use as surgical masks.

1. 产品:

N95型过滤材料 (过滤效果达95%)
防油雾效能高。

2. 注意事项:

- A: 不要在氧气比例小于19.5%的情况下使用
- B: 有某些身体疾病的人不宜使用
- C: 不要超过标准规定的最大数值
- J: 选择口罩一定要适宜, 不然会对人的身体产生危害, 甚至导致死亡
- M: 所选择使用的口罩要符合MSHA, OSHA和其他的规定标准
- O: 参照说明书使用和保养口罩
- P: 此认证不评估外科手术口罩



- 1、如上图左手托持口罩，金属鼻条夹向上。
- 2、下颚抵于口罩，右手顺势将松紧带往上向后拉，置于头顶。
- 3、将另外一条松紧带拉置于颈部。
- 4、两手轻压金属鼻夹，使其贴合脸部。



注意与警告

- 1、留胡子或其它毛发会妨碍口罩密封垫与脸部的密合，这种情况下不应使用。
- 2、防尘口罩与佩戴者的脸能够密合。
- 3、必要时更换，EN 标准建议应每班更换口罩。
- 4、使用任何防尘口罩之前，使用者应接受正确使用方法的培训。
- 5、本产品不能用于有害气体、蒸汽及喷漆中产生的溶剂的防护，不能用于氧气浓度低于19.5%的缺氧环境。
- 6、只能用于适当通风的氧气充足的环境。
- 7、不能用于有害物浓度达到可立即威胁生命和健康浓度的环境。
- 8、若出现下述情况，应立即离开工作区域：
 - a) 感觉呼吸困难；
 - b) 感觉恶心和其它不适。
- 9、口罩损坏时应废弃和更换。
- 10、禁止改变或修改本产品。
- 11、在暴露期间未一直按照佩戴方法和警告使用本产品会降低防护有效性，并可导致疾病或永久性健康伤害。



港凯

GANGKAI

制造商：上海港凯净化制品有限公司
Shanghai Gangkai Purifying Products Co.,Ltd.

地址：上海松江出口加工区车墩分区香亭路

服务热线：021-57775403-5

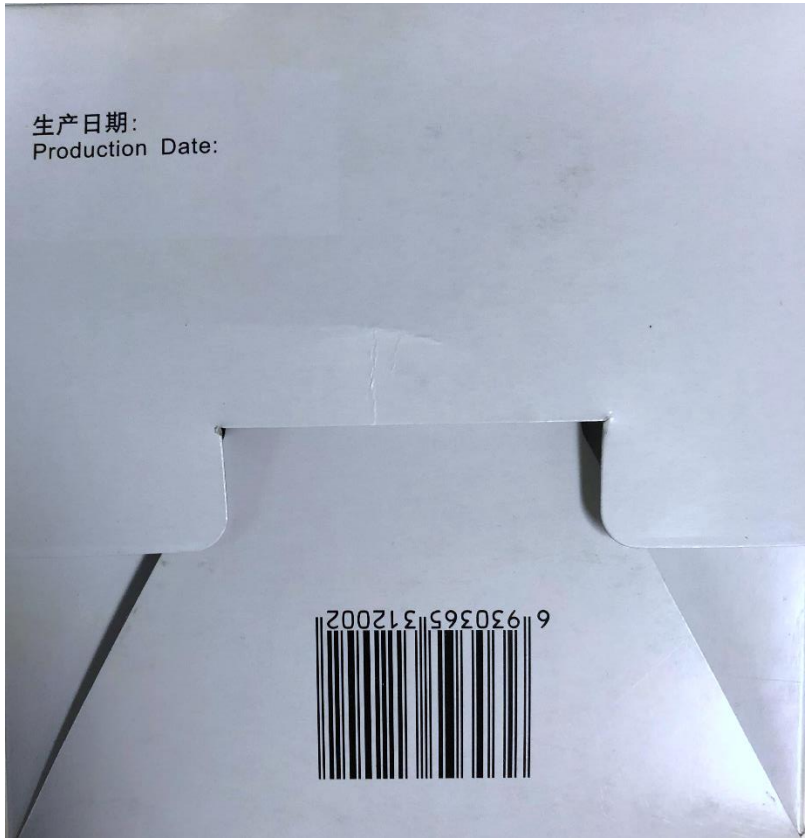
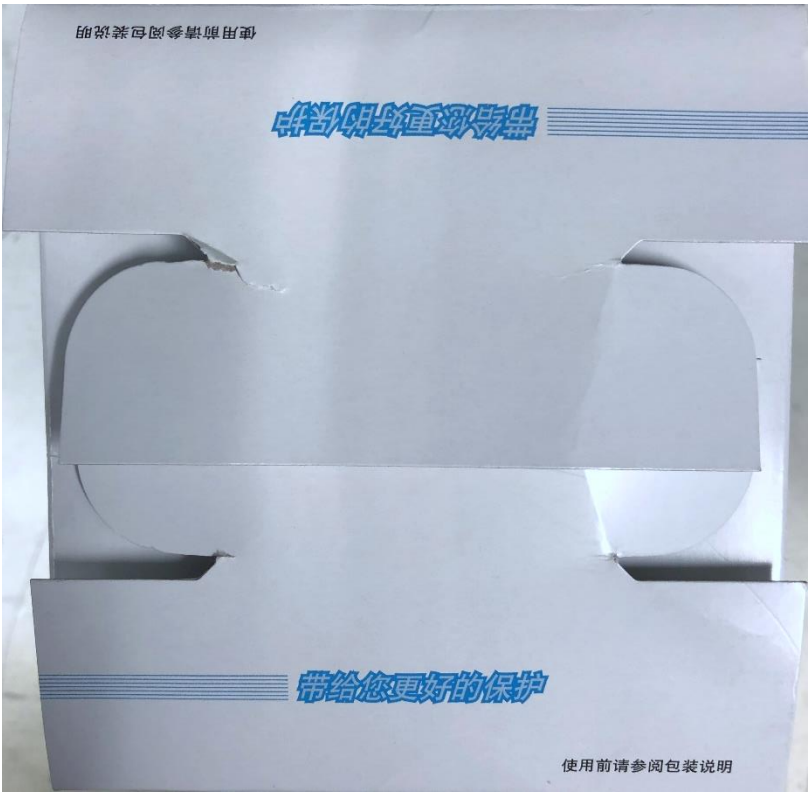
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- 工业产品许可证：XK20-301-00193
- 通过国际质量ISO9001管理体系认证

**NIOSH Approved
Respirator**
美国职业安全与健康
研究所认证口罩

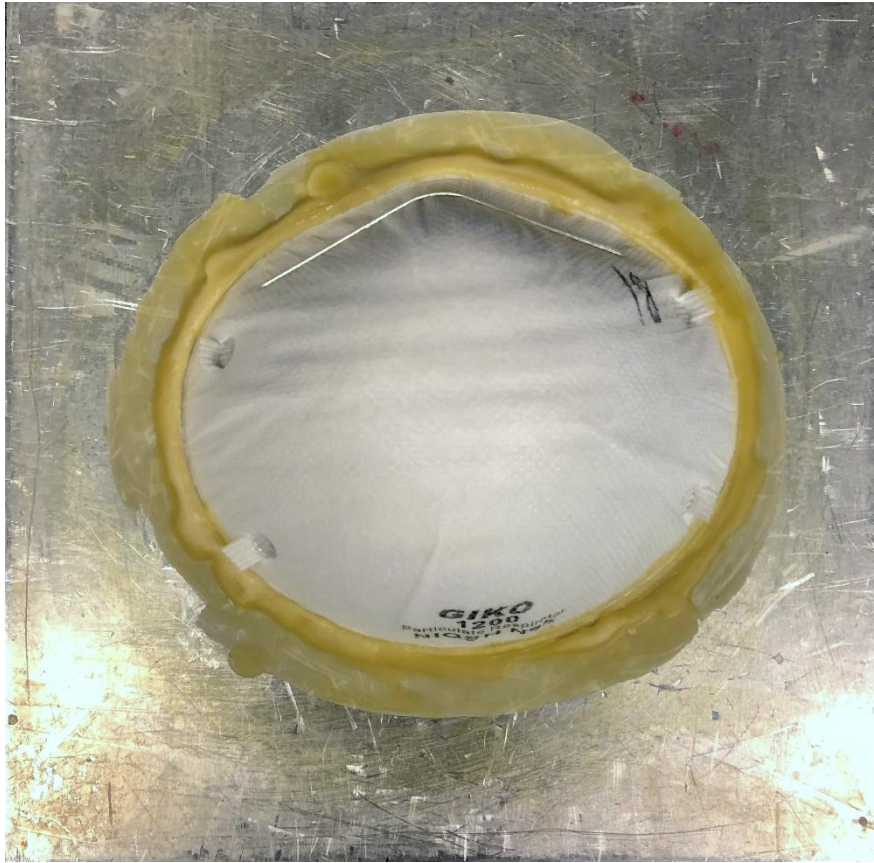
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