



Changsha Jneyl Medical Equipment Co.Ltd

# Changsha JNEYL Medical Equipment Co. Ltd

**JNEYL**金纳尔

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## Company Introduction

Changsha JNEYL Medical Equipment Co., Ltd. is located in Changsha E-center, the national demonstration medicine park in Liuyang Economic Development Zone, Changsha. It mainly produces and sells all types of medical device products, including disposable protective face mask, KN95 protective face mask, disposable medical face mask, disposable medical surgical face mask, medical N95 face mask, child protective face mask. The company invested more than 10 million of RMB, There are currently ten production lines for KN95 masks with a daily production capacity of over 100,000. There are six production lines for disposable face masks, with daily output exceeding 600,000. All medical products have been filed and submitted for inspection in the Provincial Drug Supervision Department, holds Class II medical device registration certificate and production license. The company adheres to the business philosophy of "integrity management, good morals" and dedicated to the society with the best products and services. Our company is a key contact company of Hunan Provincial Development and Reform Commission for coronavirus prevention and control, actively responding to the national call for epidemic prevention, it has received widespread attention from the government and society, and has been reported by the media many times. The company has introduced domestic and foreign advanced equipment production equipment and quality testing tools, as well as a production workshop with a standard of 100,000 level or more. It has professional management personnel, technical research personnel and a strong sales team, effectively ensure the safety and effectiveness of the product, and improved the company's market competitiveness at domestic and foreign. And the company is qualified for independent import and export trade, and has obtained CE / FDA certification for related products.

## MAIN PRODUCTS



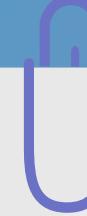
**KN95 grade protective face mask without breathing valve**



**KN95 grade child protective mask**



**Disposable medical respirator (Non-sterile)**



**Disposable Medical face mask (Non-sterile)**



# Applicable Environment



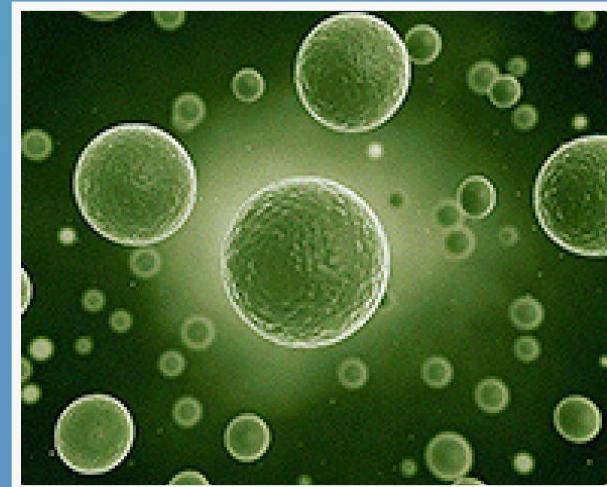
▲ Smog



▲ Dust



▲ Bacterial



▲ Virus



▲ Formaldehyde



▲ Droplets

# KN95 protective mask without breathing valve

- 1.3D three-dimensional breathable tailoring、Fit to face、High elastic earband.
- 2.Can prevent patients from spraying droplets, reducing droplet volume and spraying speed.
- 3.Can block virus-containing droplets and prevent inhalation by the wearer  
The three-dimensional stretch design fully fits the face, and the ventilation is smooth and unobstructed.

Filtering effect  $\geq 95\%$

Implementation standards: GB 2626-2006



Brand	JNEYL	Color	White
Model	JNRYL-2802	Layers	Four-layer filtration
Material	Non-woven	Function	Dust / Haze / Germs / Flu
Storage method	Shady / ventilated / dry	Packing	Boxed / Plastic Packaging

# KN95 protective mask without breathing valve

JNEYL 金纳尔

Safe and secure, Fit comfortably, Strong protection



Size: 10\*10cm

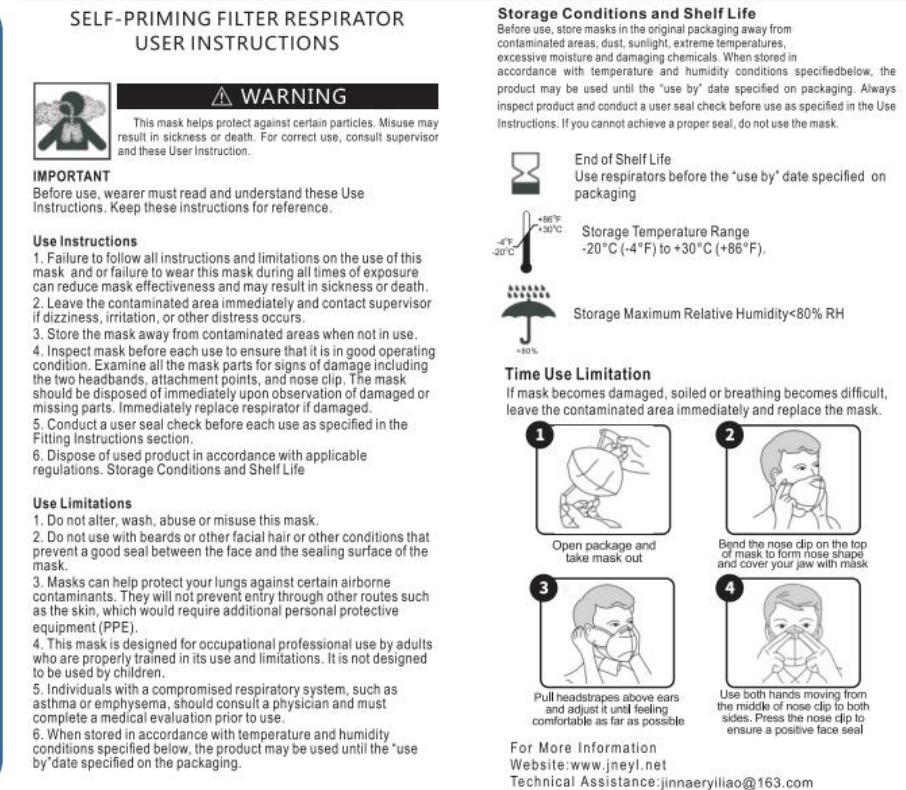
Filtering effect  $\geq 95\%$

- Safe and secure
- Fit comfortably
- Strong protection

JNEYL  
金纳尔医疗



# KN95 face mask box



盒子包装尺寸：320\*150\*120  
一盒50



纸箱尺寸：660\*620\*330MM  
20盒一箱

KN95 Packing specifications: one box of 50, Size:32\*12\*15cm;  
one box of 20 boxes, size : 66 \* 62 \* 33cm.  
Can be customized according to actual needs.

## KN95 grade child protective mask

Four-layer protection: The outer layer and mouth layer are non-woven; The middle two layers are hot air cotton and melt-blown cloth.

Can prevent patients from spraying droplets, reducing droplet volume and spraying speed.

Can block virus-containing droplet cores and prevent inhalation by the wearer

The three-dimensional stretch design fully fits the face, and the ventilation is smooth and unobstructed.

**Size:** 10cmX8cm

**Implementation standards:**

**GB 2626-2006 KN95**



有效防尘

EFFECTIVE DUST



面料舒适

FABRICS IS COMFORTABLE



4层防护

FOUR LAYERS OF PROTECTION



符合标准

CONFORM TO THE STANDARD

**Filtering effect $\geq 95\%$**



Brand	JNEYL	Color	White
Model	JNRYL-2802	Layers	Four-layer filtration
Material	Non-woven	Function	Dust / Haze / Germs / Flu
Storage method	Shady / ventilated / dry	Packing	Boxed / Plastic Packaging

# Disposable medical respirator(Non-sterile)

**JNEYL**金纳尔

Filtering effect $\geq$ 95%

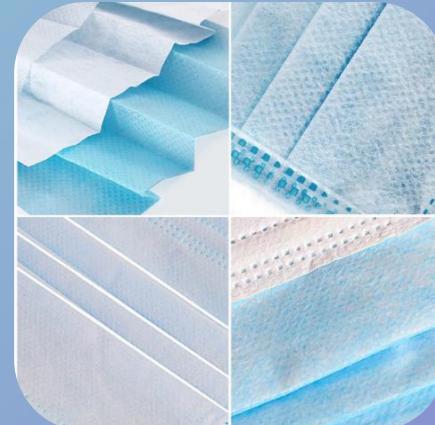


Breathable

Snug fit

Protective

Low respiratory resistance



Brand	JNEYL	Color	Blue
Model	Flat	Layers	Three-layer filtration
Material	Non-woven	Funvtion	Dust/Haze/Germs/Flu
Storage method	Shady / ventilated / dry	Packing	Boxed / Plastic Packaging

This product consists of a mask body, a nose clip, and earband, the inner and outer layers of the mask are made of non-woven material, intermediate layer is polypropylene meltblown cloth, nose clip made of plastic material, and the mask band is made of elastic material or non-woven fabric. Non-sterile supply..

It is suitable for the health care of the wearer in the general medical environment without the risk of body fluids and splashes.

Size: 17.5X9.5CM Implementation standards: YY/T 0969-2013



Implementation standards: YY/T 0969-2013 《Disposable medical face mask》



# Packaging Diagram of Disposable Medical Mask

JNEYL 金纳尔



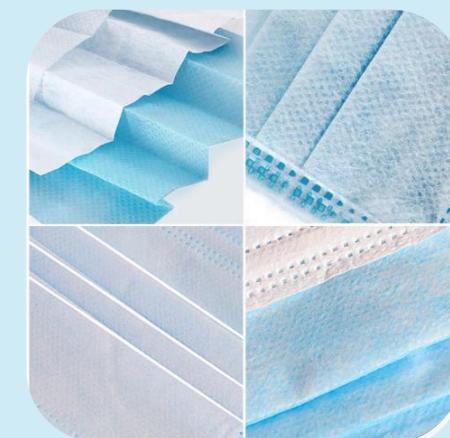
Disposable mask packaging specifications: one box of 50, one box of 40 boxes, carton packaging.  
size: 57 \* 46 \* 47cm

# Disposable surgical mask (Non-sterile)

Brand	JNEYL	Color	rule
Model	flat	Layer	Triple filtration
Material	Non-woven	function	Dust / smog / germs / flu
storage	cool / ventilated / dry	Packing	box/opp bag

This product is composed of mask body, nose clip and mask belt. The outer layer of the mask is made of non-woven material. The intermediate layer is polypropylene fused spray cloth. Non-sterile supply. It is suitable for the disposable mask worn by clinical medical personnel in the process of invasive operation. Disposable surgical mask worn by clinical medical personnel during invasive operation is used to cover the mouth, nose and jaw of the user, providing a physical barrier to prevent the direct passage of pathogens, microorganisms, body fluids and particles. The standard stipulates that the filtration efficiency of the mask should be no less than 95%

**Filtering effect≥95%**



Low respiratory resistance  
Breathable not leaky  
Comfortable fit  
Strong defensive

Implementation Standard: YY 0469-2011  
Dimensions: 17.5X9.5CM



Executive Standard: YY 0469-2011 "Medical Surgical Mask"

# Disposable surgical mask (Non-sterile)

JNEYI 金纳尔



Medical surgical mask packaging specifications: one box of 50, one box of 40 boxes, carton packaging  
size: 57 \* 46 \* 47cm weight 10KG

- Business license



Disposable medical face masks and medical surgical masks were agreed to be included in the emergency approval of medical devices

湖南省医疗器械应急审批  
结果通知单

(编号: 湘械应急 2020-0251)

长沙金纳尔医疗器械有限公司:

产品名称: 一次性使用医用口罩

性能结构及组成: /

产品管理类别: 第二类医疗器械

经审查, 审查结论为: 同意纳入医疗器械应急审批。

特此通知。

湖南省药品监督管理局

(盖章)

日期: 2020 年 2 月 27 日

湖南省医疗器械应急审批  
结果通知单

(编号: 湘械应急 2020-0250)

长沙金纳尔医疗器械有限公司:

产品名称: 医用外科口罩

性能结构及组成: /

产品管理类别: 第二类医疗器械

经审查, 审查结论为: 同意纳入医疗器械应急审批。

特此通知。

湖南省药品监督管理局

(盖章)

日期: 2020 年 2 月 27 日

## • Medical Device Registration Certificate

**中华人民共和国医疗器械注册证**

注册证编号：湘械注准20202140398

注册人名称	长沙金纳尔医疗器械有限公司
注册人住所	浏阳经开区湘台路18号长沙E中心一期B4栋二层01号房
生产地址	浏阳经开区湘台路18号长沙E中心一期B4栋二层01号房
代理人名称	不适用
代理住所	不适用
产品名称	一次性使用医用口罩（非无菌型）
型号、规格	型号：平面形耳挂式；规格：17.5cm×9.5cm（允差±5%）。
结构及组成	由口罩体、鼻夹、口罩带组成，口罩体内外层由无纺布材料制造而成，中间层为聚丙烯熔喷布，鼻夹为可塑性材料制成，口罩带由弹性材料制成。产品非无菌供应。
适用范围	适用于佩戴者在无体液和喷溅风险的普通医疗环境下的卫生护理。
附件	产品技术要求
其他内容	
备注	1. 该产品为应急审批注册，有效期为八个月；2. 该产品在延续/变更注册时应按医疗器械注册管理要求完善相关资料。

审批部门：湖南省药品监督管理局

批准日期：2020年03月12日  
有效期限：2020年11月11日

(盖章)

(翻译专用章)

**Medical Device Registration Certificate of the People's Republic of China**

Registration Certificate No: XXZH 20202140398

Registrant Name	Changsha Jneyl Medical Equipment Co., Ltd
Domicile of Registrant	Building B4, Xiangtai Road, Changsha E Center , Liuyang Biomedical Industrial Park, Changsha City, Hunan Province, China
Production Address	Building B4, Xiangtai Road, Changsha E Center , Liuyang Biomedical Industrial Park, Changsha City, Hunan Province, China
Agent's Name	Not Applicable
Agent's Domicile	Not Applicable
Product Name	Disposable Medical Masks(Non Sterile Type)
Model, Specification	Type: Flat ear hanging type; Specification: 17.5cm × 9.5cm (permissible variation ±5)
Structure and Composition	The mask is composed of mask body, nose clip and mask belt. The outer layer of the mask is made of non-woven materials, the middle layer is polypropylene melt blown cloth, the nose clip is made of plastic materials, and the mask belt is made of elastic materials. Product is not sterile supply.
Scope of Application	The product is applicable to the health care of the wearer in the general medical environment without the risk of body fluid and splash.
Attachment	Product technical requirements
Others	
Remarks	1. The product is an emergency approval registration with validity period of eight months; 2. When the product continues / changes the registration, the relevant materials shall be improved according to the requirements of medical machinery registration management.

Approved by: Hunan Drug Administration

Approval Date: Mar. 12, 2020  
Expiry Date: Nov. 11, 2020  
Hunan Drug Administration  
Special Seal for Medical Device Registration (Seal)

## • Medical Device Registration Certificate

**中华人民共和国医疗器械注册证**

注册证编号：湘械注准20202140397

注册人名称	长沙金纳尔医疗器械有限公司
注册人住所	浏阳经开区湘台路18号长沙E中心一期B4栋二层01号房
生产地址	浏阳经开区湘台路18号长沙E中心一期B4栋二层01号房
代理人名称	不适用
代理人住所	不适用
产品名称	医用外科口罩（非无菌型）
型号、规格	型号：平面形耳挂式；规格：17.5cm×9.5cm（允差±5%）。
结构及组成	由口罩体、鼻夹、口罩带组成，口罩内外层由无纺布材料制造而成，中间层为聚丙烯熔喷布，鼻夹为可塑性材料制成，口罩带由弹性材料制成。产品非无菌供应。
适用范围	适用于医务人员或相关人员的基本防护，以及在有创操作过程中阻止体液和喷溅物传播的防护。
附件	产品技术要求
其他内容	
备注	1. 该产品为应急审批注册，有效期为八个月；2. 该产品在延续/变更注册时应按医疗器械注册管理要求完善相关资料。

审批部门：湖南省药品监督管理局

批准日期：2020年03月12日  
有效期至：2020年11月11日

**Medical Device Registration Certificate of the People's Republic of China**

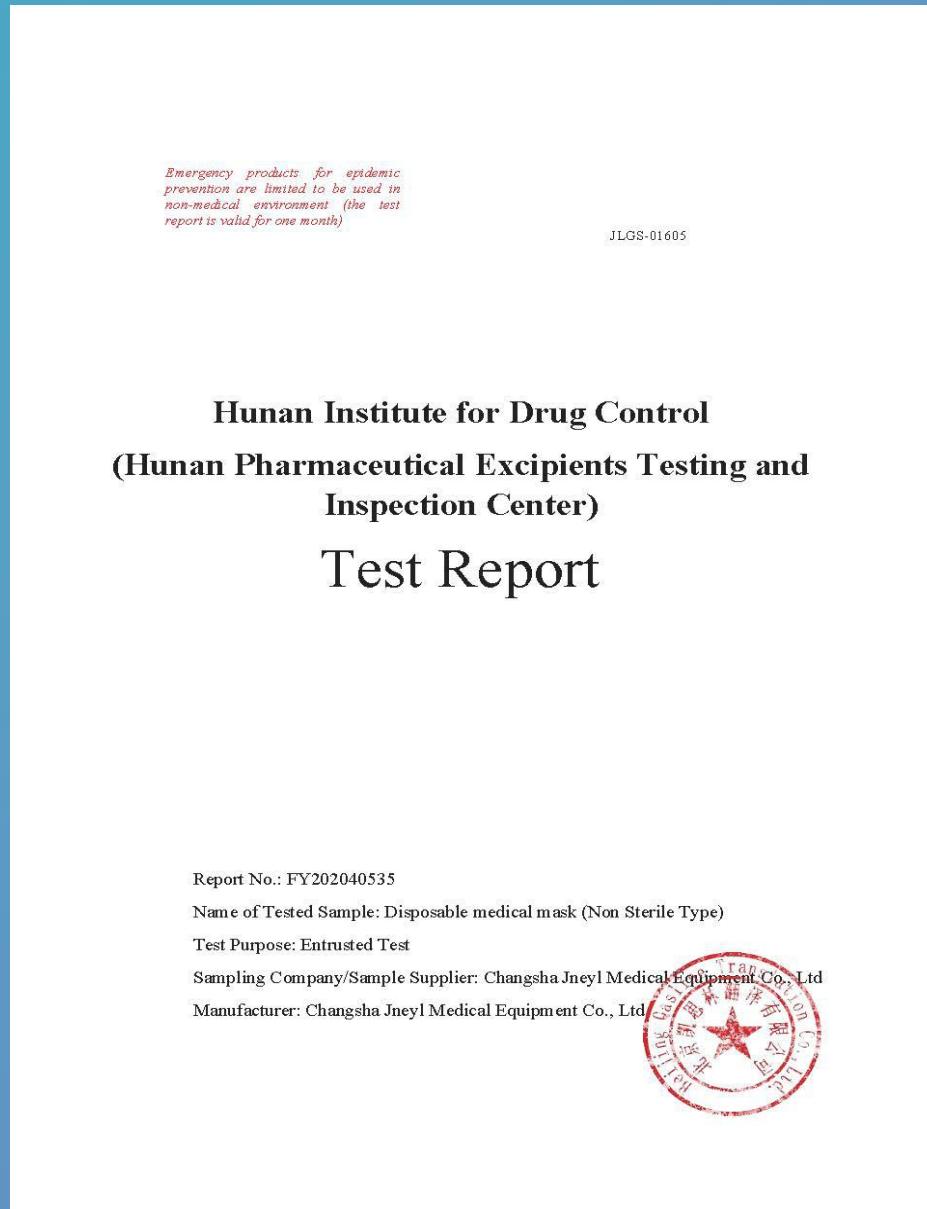
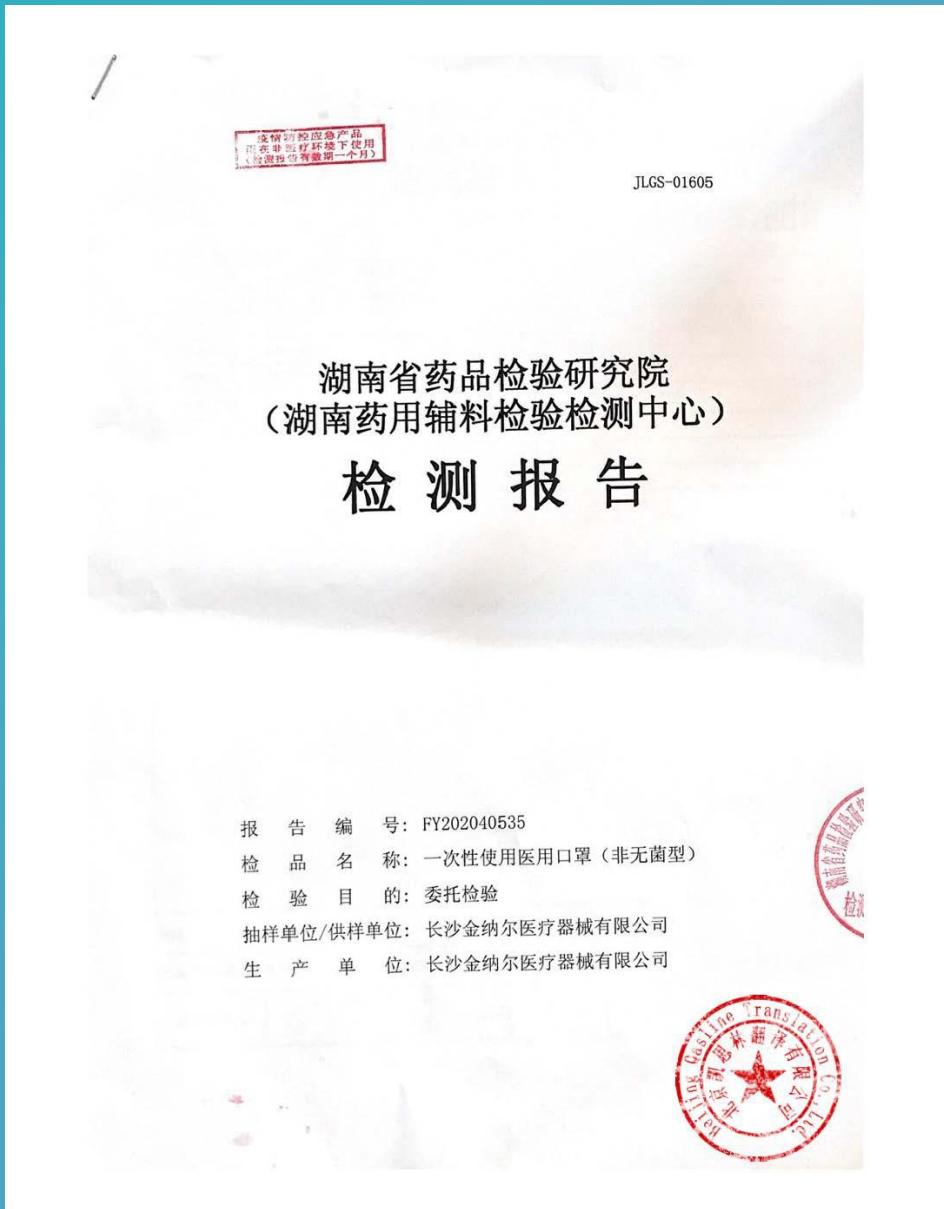
Registration Certificate No: XXZH 20202140397

Registrant Name	Changsha Jneyl Medical Equipment Co., Ltd
Domicile of Registrant	Building B4, Xiangtai Road, Changsha E Center , Liuyang Biomedical Industrial Park, Changsha City, Hunan Province, China
Production Address	Building B4, Xiangtai Road, Changsha E Center , Liuyang Biomedical Industrial Park, Changsha City, Hunan Province, China
Agent's Name	Not Applicable
Agent's Domicile	Not Applicable
Product Name	Medical Surgical Mask(Non Sterile Type)
Model, Specification	Type: Flat ear hanging type; Specification: 17.5cm×9.5cm (permissible variation ±5)
Structure and Composition	The mask is composed of mask body, nose clip and mask belt. The outer layer of the mask is made of non-woven materials, the middle layer is polypropylene melt blown cloth, the nose clip is made of plastic materials, and the mask belt is made of elastic materials. Product is not sterile supply.
Scope of Application	The product is applicable to the basic protection of medical or related personnel, as well as the protection of tissue fluids and splashes in the process of invasive operation.
Attachment	Product technical requirements
Others	
Remarks	1. The product is an emergency approval registration with validity period of eight months; 2. When the product continues / changes the registration, the relevant materials shall be improved according to the requirements of medical machinery registration management.

Approved by: Hunan Drug Administration

Approval Date: Mar. 12, 2020  
Expiry Date: Nov. 11, 2020  
Hunan Drug Administration  
Special Seal for Medical Device Registration (Seal)

- Test report of disposable medical mask



## • Test report of disposable medical mask



Hunan Institute for Drug Control  
(Hunan Pharmaceutical Excipients Testing and Inspection Center)

*Special Seal for Test Report of Hunan Institute for Drug Control*  
*Hunan Pharmaceutical Excipients Testing and Inspection Center (Seal)*

### Test Report

Report No.: FY202040535

Page 1 of 1

Name of Tested Sample	Disposable medical mask (Non Sterile Type)	Inspection No.	FY202040535
Manufacturer/Place of Origin	Changsha Jneyl Medical Equipment Co., Ltd	Batch No./Production Date	20200226
Dosage Form/Category	Other	Specification/Level	17.5cm×9.5cm
Test Purpose	Entrusted Test	Packaging Specification	/
Test Item	Single Item Test	Valid to/Validity	1 year
Receiving Date of Sample	2020-02-27	Quantity of Tested Sample	30 pieces
Sampling Company/Sample Supplier	Changsha Jneyl Medical Equipment Co., Ltd		
Sampled Company	/		
Test Standard	YY/T 0969-2013 Disposable medical mask		
Test Item	Standard Regulation	Test Result	
4.5 bacterial filtration efficiency (BFE)	shall not be less than 95%	99.9%	

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*Responsible for samples only*

Note: /

Conclusion: According to the requirements of the sample supplier, the above items were inspected with reference to YY/T 0969-2013 Disposable medical mask, and the result is shown as above.

Authorized Signatory	李长喜 (Signature)	Date of Issue
		2020-03-01



## • Medical surgical mask test report



湖南省医疗器械检验检测所  
检 验 报 告 首 页

报告编号: YQ202030261 第1页共2页

样品名称	医用外科口罩	样品编号	YQ202030261
型号规格	平面形 17.5cm×9.5cm	商 标	/
委托单位	长沙金纳尔医疗器械有限公司	检验类别	注册检验
委托单位地址	湖南省长沙市浏阳生物医药工业园长沙E中 心湘台路B4栋	产品编号 / 批号	2020022802
生产单位	长沙金纳尔医疗器械有限公司	抽样单/协议编号	QX202000450
受检单位	长沙金纳尔医疗器械有限公司	生产日期	20200228
抽样单位	/	样品数量	50 个
抽样地点	/	抽样基数	/
抽样日期	/	检验地点	本所实验室
收样日期	2020-02-29	检验日期	2020-03-01 ~ 2020-03-02
检验项目	部分检验		
检验依据	长沙金纳尔医疗器械有限公司医用外科口罩产品技术要求		
检验结论	被检样品受检项目符合长沙金纳尔医疗器械有限公司医用外科口罩产品技术要求 <small>(检验报告专用章或检验单位公章)</small> <small>签发日期 2020-03-02</small>		
备注	1) 报告中的“—”表示此项不适用，报告中“/”表示此项空白。 2) 应急注册检验，本品为非无菌产品。		

批准:   
职务: 副所长

审核:   
易 薇

批号:   
职务: 副所长

湖南省医疗器械检验检测所  
检 验 报 告

报告编号: YQ202030261 第2页共2页

序号	检验项目	标准条款	标准要求	检验结果	单项结论	备注
1	颗粒过滤效率	2.7	过滤效率不低于30% (3/0)	98%~99% (3/0)	符合	
2	合成血液穿透	2.9	口罩内侧面不应出现渗透 (3/0)	符合要求 (3/0)	符合	

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# Medical surgical mask test report in English

## Test Report

Report No.: YQ202030261



Applicant: Changsha Jneyl Medical Equipment Co., Ltd

Sample Name: Medical Surgical Mask

Model: Flat 17.5cm×9.5cm

Test Type: Registration Test

Hunan Testing Institute for Medical Devices



Hunan Testing Institute for Medical Devices  
First Page of Test Report

Page 1 of 2

Report No.: YQ202030261



Sample Name	Medical Surgical Mask	Sample No.	YQ202030261
Model Specification	Flat 17.5cm×9.5cm	Brand	/
Applicant	Changsha Jneyl Medical Equipment Co., Ltd	Test Category	Registration Test
Address of Applicant	Building B4, Xiangtai Road, Changsha E Center , Liuyang Biomedical Industrial Park, Changsha City, Hunan Province, China	Product No./Batch No.	2020022802
Manufacturer	Changsha Jneyl Medical Equipment Co., Ltd	Sampling list/Agreement No.	QX202000450
Tested Company	Changsha Jneyl Medical Equipment Co., Ltd	Production Date	20200228
Sampling Company	/	Sample Quantity	50 pieces
Sampling Location	/	Sampling Base	/
Sampling Date	/	Place of Test	Laboratory of The Institute
Receiving Date of Sample	2020-02-29	Date of Test	2020-03-01 ~ 2020-03-02
Test Item	Partial Test		
Test Standard	Technical Requirements for Medical Surgical Masks of Changsha Jneyl Medical Equipment Co., Ltd		
Test Conclusion	The tested items of the test samples meet the technical requirements for Medical Surgical Masks of Changsha Jneyl Medical Equipment Co., Ltd .		
	<i>Special Seal for Test Report of Hunan Testing Institute for Medical Devices</i> (Special Seal for Test Report or Official Seal of Testing Institute) Date of Issue: 2020-03-05		
Note	1) The symbol "—" in the report means this item is not applicable, and the one "/" in the report means this item is blank.  2) This product is proved to be non sterile through the emergency registration test.		

Approved by: (Signature) Reviewed by: (Signature) Inspected by: (Signature)

Position: Deputy Director

Hunan Testing Institute for Medical Devices  
Second Page of Test Report

Report No.: YQ202030261

Page 2 of 2

No.	Test items	Standard clause	standard requirement	Test results	Single conclusion	remark
1	Particle filtration effect	2.7	Filtration effect is not less than 30%(3/0)	98%-99%(3/0)	Meet the demand	/
2	Synthetic blood penetration	2.9	The inside of the mask should not penetrate(3/0)	Meets the requirements(3/0)	Meet the demand	

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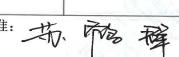
## • KN95 face mask test report



**检验检测报告 Test Report**

[2020] WSZ FHL 第 1920 号 共 3 页 第 1 页

产品名称 Product name	Kn95 口罩	规格型号 Specification	鸭嘴
委托单位/地址/联系电话 Applicant/Add/Tel	长沙金纳尔医疗器械有限公司/浏阳经开区湘台路 18 号长沙 E 中心一期 B4 栋二层 01 号房 /18796941956		
生产单位/地址/联系电话 Manufacturer/Add/Tel	长沙金纳尔医疗器械有限公司/浏阳经开区湘台路 18 号长沙 E 中心一期 B4 栋二层 01 号房 /—		
样品等级 Sample grade	KN95	样品编号 Sample number	GW 1920-2020
样品数量 Sample quantity	55 个	样品接收日期 Receiving date of sample	2020 年 03 月 10 日
检验检测类别 Test type	委托检验	货号/批号/款号 Article number/Batch number/Style number	2020030301
检验检测日期 Test date	2020/03/10~2020/03/13	检验检测地点 Test site	本公司实验室
样品状态 Sample state	符合检验检测要求		
检验检测依据 Test standard(s)	GB 2626-2006《呼吸防护用品 自吸过滤式防颗粒物呼吸器》		
检验检测项目 Test items	一般要求、外观检查、呼吸阻力、可燃性、过滤效率、头带、死腔、视野、泄漏性		
检验检测结论 Test conclusion	样品经检验，所检项目符合 GB 2626-2006 标准规定的要求，具体检验结果详见第 2-3 页。 签发日期 2020 年 3 月 17 日		
备注 Note	样品信息由委托方提供，本报告仅对来样负责。 		

批准:  审核:  检查: 

## • KN95 face mask test report

检验检测结果 Test Result						
[2020] WSZ FHL 第 1920 号						
序号 Number	检验检测项目 Test item	单位 Unit	技术要求 Technical requirement	检验检测结果 Test result	单项评价 Single item decision	
1	一般要求	—	所用材料应具有足够的强度，在正常使用寿命中不应出现破损或变形。	所用材料具有足够的强度，在正常使用寿命中未出现破损或变形。	合格	
			应不易产生结构性破损，部件的设计、组成和安装不对使用者构成任何危险；头带的设计可调，便于佩戴和摘除，应能将面罩牢固地固定在脸上，且佩戴时不应出现明显的压迫或压痛现象；尽可能具有较小的死腔和较大的视野，随弃式面罩的结构应能保证与面部的密合，且在正常使用寿命期内未出现变形。	不易产生结构性破损，部件的设计、组成和安装未对使用者构成任何危险；头带的设计可调，便于佩戴和摘除，能将面罩牢固地固定在脸上，且佩戴时未出现明显的压迫或压痛现象；具有较小的死腔和较大的视野；随弃式面罩的结构能保证与面部的密合，且未在正常使用寿命期内未出现变形。		
2	外观检查	—	样品表面不应破损、变形和有明显的其他缺陷；部件材料和结构应能耐受正常使用条件及可能遇到的温度、湿度和机械冲击；头带应可调，更换式半面罩的头带设计应为可更换；经温度湿度预处理和机械强度预处理后，部件不应脱落、损坏和变形。	样品表面未破损、变形和有明显的其他缺陷；部件材料和结构能耐受正常使用条件及可能遇到的温度、湿度和机械冲击；头带半面罩的头带设计应为可更换；经温度湿度预处理和机械强度预处理后，部件未脱落、损坏和变形。	合格	
			呼吸阻力	吸气阻力		Pa
3	呼吸阻力	呼气阻力	Pa	呼气阻力≤250	未预处理 80.1 81.7 预处理 82.6 80.5	合格
					未预处理 有燃烧 续燃时间：0.1s 有燃烧 续燃时间：0.1s 有燃烧 续燃时间：0.1s 有燃烧 续燃时间：0.1s	
4	可燃性	—	暴露于火焰的各部件在从火焰移开后，不应燃烧；如果燃烧，续燃时间不应超过 5s。	未预处理 预处理	有燃烧 续燃时间：0.1s 有燃烧 续燃时间：0.1s 有燃烧 续燃时间：0.1s 有燃烧 续燃时间：0.1s	合格

共 3 页 第 2 页

检验检测结果  
Test Result

[2020] WSZ FHL 第 1920 号

共 3 页 第 3 页

序号 Number	检验检测项目 Test item	单位 Unit	技术要求 Technical requirement	检验检测结果 Test result	单项评价 Single item decision																				
5	过滤效率	—	≥95.0%	未预处理	99.3% 99.1% 99.2% 99.1% 99.2% 99.1% 99.3% 99.2% 99.2% 99.1%	合格																			
				预处理	未预处理		未出现滑脱、断裂																		
								6	头带	—	承受 10N，持续 10s 的拉力时，不应出现滑脱或断裂。														
												7	死腔	—	≤1% 0.02%										
																8	视野	—	下方视野≥60° 75.2°						
																				9	泄漏性	—	受试者 1# 5.3 5.7 7.6 7.1 5.6 6.3 2# 4.7 7.3 6.4 6.7 4.3 5.9 3# 5.7 8.8 7.9 7.4 6.1 7.2 4# 4.5 6.3 7.6 7.7 5.0 6.2 5# 4.8 6.8 7.3 7.5 4.3 6.1 6# 4.7 7.2 7.7 5.9 4.4 6.0 7# 5.1 7.7 6.7 6.9 5.0 6.3 8# 5.1 7.3 6.6 7.0 4.6 6.1 9# 5.9 7.8 8.1 7.6 5.4 7.0 10# 4.5 6.4 6.9 7.2 4.2 5.8		
																								备注	以下空白

检验检测结果  
Test Result

[2020] WSZ FHL 第 1920 号

共 3 页 第 3 页

- English translation of KN95 mask test report



## Test Report

(2020) WSZ FHL No. 1920

**Product Name:** Kn95 Face Mask

**Applicant:** Changsha Jneyl Medical Equipment Co., Ltd

**Manufacturer:** Changsha Jneyl Medical Equipment Co., Ltd

**Test Type:** Entrustment Inspection

Jiangsu Guojian Testing Technology Co., Ltd.

*Special Seal for Inspection of Jiangsu Guojian Testing Technology Co., Ltd.  
(Seal)*



**Test Report**

[2020] WSZ FHL No. 1920				Page 1 of 3
Product Name	Kn95 face mask	Specification	Duckbill mask	
		Brand	—	
Applicant/Add/Tel	Building B4, Xiangtai Road, Changsha E Center, Liuyang Biomedical Industrial Park, Changsha City, Hunan Province, China / Changsha Jneyl Medical Equipment Co., Ltd/18796941956			
Manufacturer/Add/Tel	Building B4, Xiangtai Road, Changsha E Center, Liuyang Biomedical Industrial Park, Changsha City, Hunan Province, China / Changsha Jneyl Medical Equipment Co., Ltd			
Sample Grade	KN95	Sample Number	GW 1920-2020	
Sample Quantity	55 个	Receiving Date of Sample	Mar. 10, 2020	
Test Type	Entrustment inspection	Article Number/Batch Number/Style Number	2020030301	
Test Date	2020/03/10~2020/03/13		Test Site	Our Test Laboratory
SAMPLE STATE	Meet the inspection and testing requirements			
Test Standard(s)	GB 2626-2006 Respiratory Protective Equipment - Air-breaking Filter Type Anti-particulate Respirator			
Test Items	General requirements, visual inspection, respiratory resistance, flammability, filtration efficiency, headband, dead space, field of vision, leakage			
Test Conclusion	After the sample is tested, the tested items meet the requirements of GB 2626-2006 standard. Please refer to page 2-3 for the specific test results. Date of issue: Mar. 17, 2020 <i>Special Seal for Inspection of Jiangsu Guojian Testing Technology Co., Ltd. (Seal)</i>			
Note	The sample information is provided by the entrusting party, and this report is only responsible for the receiving samples. 			

Approved by: *王平 魏巍 (Signature)* Checked by: *王平 (Signature)* Inspect by: *杨莹 (Signature)*

*Special Seal for Inspection of Jiangsu Guojian Testing Technology Co., Ltd. (Seal)*

- In the test results of KN95 masks, all the filtering effects were greater than 95%

Test Result					
[2020] WSZ FHL No. 1920			Page 2 of 3		
No.	Test item	Unit	Technical Requirement	Test Result	Single Item Decision
1	General requirements	—	The materials used shall have sufficient strength and shall not be damaged or deformed in normal service life. It shall not be easy to have structural damage, and the design, composition and installation of components shall not pose any danger to the user; the design of headband shall be adjustable, easy to wear and remove, and the mask shall be firmly fixed on the face with the help of headband. There shall be no obvious compression or tenderness when wearing; it shall have a smaller dead space and a larger field of vision as far as possible; the structure of disposable mask shall be able to ensure the close connection with the face, and there is no deformation during the normal service life.	The materials used have sufficient strength and not be damaged or deformed in normal service life. It is not easy to have structural damage, and the design, composition and installation of components do not pose any danger to the user; the design of headband is adjustable, easy to wear and remove, headband can firmly fix the mask on the face, and there is no obvious compression or tenderness when wearing; it has a smaller dead space and a larger field of vision; the structure of disposable mask can ensure the close contact with the face, and there is no deformation during the service life.	Qualified
2	Visual inspection	—	The sample surface shall not be damaged, deformed and have obvious other defects; the component material and structure shall be able to withstand normal use conditions and possible temperature, humidity and mechanical impact; the headband shall be adjustable, the headband design of the replacement half mask shall be replaceable; after the temperature and humidity pretreatment and mechanical strength pretreatment, the component shall not fall off, damage and have deformation.	The sample surface has no damage, deformation and other obvious defects; the component material and structure can withstand normal use conditions and possible temperature, humidity and mechanical impact; the headband is adjustable; after temperature and humidity pretreatment and mechanical strength pretreatment, the component is not falling off, damaged and deformed.	Qualified
3	Respiratory resistance	Pa	Inspiratory resistance $\leq 350$	Without pretreatment: 101.3 With pretreatment: 102.6 101.2 98.7	Qualified
			Exhalation resistance $\leq 250$	Without pretreatment: 80.1 With pretreatment: 81.7 82.6 80.5	Qualified
4	Flammability	—	Each part exposed to the flame shall not burn after being removed from the flame; if burning, the continuous duration shall not exceed 5S.	Burning Burning continuous duration: 0.1S Burning Burning continuous duration: 0.1S Burning Burning continuous duration: 0.1S Burning Burning continuous duration: 0.1S	Qualified

Test Result					
[2020] WSZ FHL No. 1920			Page 3 of 3		
No.	Test item	Unit	Technical Requirement	Test Result	
5	Filtration efficiency	—	$\geq 95.0\%$	Without pretreatment	
				99.3%	
				99.1%	
				99.2%	
				99.1%	
				99.2%	
				99.1%	
				99.3%	
				99.2%	
				99.1%	
6	Headband	—	No slip or fracture is allowed under 10N tension for 10S	Without pretreatment	
				Pretreatment	
				No slip, fracture are found	
				Without pretreatment	
				Pretreatment	
				No slip, fracture are found	
7	Dead space	—	$\leq 1\%$	0.02%	
8	Field of vision	—	Lower field of vision $\geq 60^\circ$	75.2°	
9	Leakage	—	Subject TIL < 11% for at least 46 of 50 actions; TIL < 8% for at least 8 of 10 subjects.	Subject	D1 (%) 1# 5.3 2# 4.7 3# 5.7 4# 4.5 5# 4.8
				D2 (%) 5.7 7.3 6.4 6.7 6.3	7.1 4.3 5.9 6.1 6.1
				D3 (%) 7.6 6.7 7.9 7.4 7.2	5.6 4.3 5.9 6.1 7.2
				D4 (%) 7.1 6.7 7.4 7.7 7.7	5.0 4.3 5.9 5.0 6.2
				D5 (%) 5.6 4.3 5.9 6.1 6.1	6.2 4.3 6.0 6.1 6.1
				TIL (%) 6.3 7.2 5.9 4.4 6.0	6.3 5.9 5.9 6.0 6.0
				Without treatment	6# 4.7 7# 5.1 8# 5.1 9# 5.9 10# 4.5
				Pretreatment	7.2 6.7 6.6 7.0 6.4
					4.4 5.0 4.6 6.1 5.8
					6.0 6.3 6.1 7.0 5.8
					5.9 6.1 5.4 7.0 5.8
				Remarks	-----

Blank below

- FDA certification





## • CE certification



### Attestation of Conformity

No. ICR Polska/3201231



Name and address of Registered Manufacturer:

Changsha Jneyl Medical Equipment Co., Ltd.  
Building B4, Changsha E center, Liuyang Biomedical Industrial Park, Changsha City, Hunan Province

Product name:

Disposable medical mask

Product type/model:

JL2020

Trade mark:

N/A

**This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.**

Relevant EC Directive: Medical Device Directive 93/42/EEC

Conformity assessment procedure: EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)

Classification: Class I according Rule 1 of Annex IX of Directive 93/42/EEC

Applied normative documents: EN 14683:2019

Applied Quality Management System

This AOC will remain valid only if Quality Management System Certificate remains valid.

The assessment process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test report made by:

- STS Testing (Shenzhen) Technology Co., Ltd.

No. of test report: MDD01M2003036

Issue date: 23.03.2020

Expiration date: 22.03.2025

The mutual obligations and rights of the certification are regulated by the contract

No. ICR Polska/2020-3125.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.



Director: Rafał Kalinowski

Warsaw, 23. 03. 2020.

ICR Polska Co. Ltd.  
ul. Plac Przymierza 6, 03-944 Warsaw  
www.icrpolska.com, e-mail: icrpolska@icrqja.com



### Certificate

No. ICR Polska/3200232



Name and address of certificate owner:

Changsha Jneyl Medical Equipment Co., Ltd  
Building B4, Changsha E center, Liuyang Biomedical Industrial Park, Changsha City, Hunan Province

Name and address of manufacturer:

Changsha Jneyl Medical Equipment Co., Ltd  
Building B4, Changsha E center, Liuyang Biomedical Industrial Park, Changsha City, Hunan Province

Product name:

Protective mask

Product types:

N95

Product trademark: JNEYL

**This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425**

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC-P-07-07. Evaluation has been carried out in accordance with test reports made by STS Testing(Shenzhen) Technology Co., Ltd.

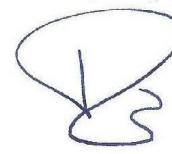
No. of test reports: PPE01P200309006

Certificate issue date: 23.03.2020

Expiration date: 22.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3109.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.

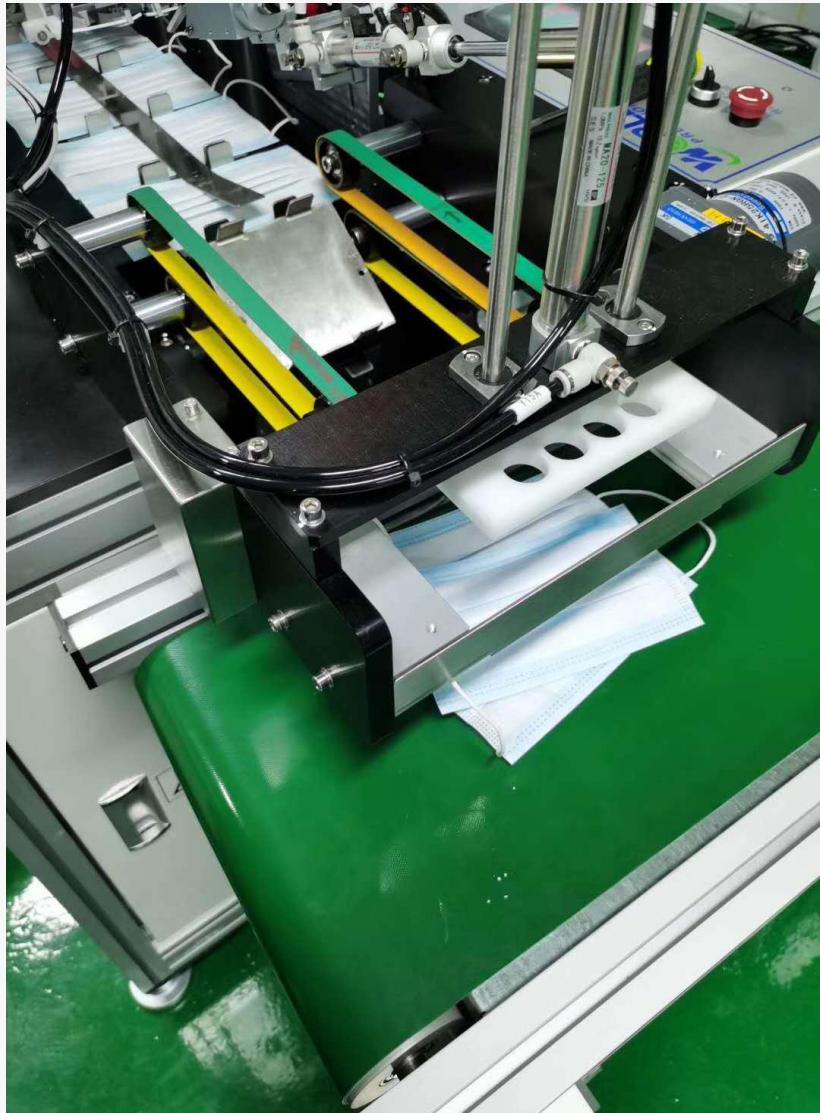


Director: Rafał Kalinowski

Warsaw, 23. 03. 2020

ICR Polska Co. Ltd.  
ul. Plac Przymierza 6, 03-944 Warsaw  
www.icrpolska.com, e-mail: icrpolska@icrqja.com





# There are many media reports on our company.



## There are many media reports on our company.



Apple Inc. purchases face masks from JNEYL Medical Equipment Co.,Ltd,And donated 10 million pcs masks to American medical institution.

# There are many media reports on our company.

JNEY | 金纳尔

## 支持疫情防控 又一家“湘字号”口罩厂即将投产



发布日期：03-09 22:04 红网官方帐号

**红网时刻3月8日讯**（通讯员 吴媛媛 记者 郭微仙）受新冠肺炎疫情影响，全国口罩面临供不应求的局面。为支持疫情防控，近日，又一家“湘字号”口罩厂积极响应号召，即将全面投产。

这家口罩厂名为长沙金纳尔医疗器械有限公司（简称长沙金纳尔），日前在湖南浏阳经开区正式成立。在该公司生产车间里，全自动化口罩设备正在进行最后的调试。

据悉，工厂拥有2500平方米洁净度10万级标准的厂房，是一家专门生产销售口罩的医疗器械公司，其中口罩成型区、口罩切边区、鼻梁条贴合区、耳带电焊区均位于10万级洁净区区域，生产场地人流和物流通道分开。

记者了解到，该公司产品采用优质无纺布并经环氧乙烷灭菌，根据通用型一次性医用口罩的尺寸要求或客户需求的尺寸进行设计制作，符合YY/T0969-2013的技术要求。

针对防护级别更高的KN95口罩，该公司的相关产品采用鸭嘴形状，并带有呼吸阀，提升了口罩的防水性与颗粒过滤效率，而鸭嘴形设计能够更好地使口罩与面部贴合。同时，该公司还将生产高滤级儿童口罩，更好保护青少年的健康。

长沙金纳尔生产负责人介绍，口罩原材料经过进厂检验、成型、压合、贴合、点焊、内包装封口、箱装、灭菌等工艺，抗湿性、合成血液穿透、细菌过滤效率、非油性颗粒过滤效率、呼吸阻力、微生物指标等方面都进行了测试，指标性能优于行业平均水平。

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根据相关要求，该公司已获得长沙市市场监督管理局的口罩应急备案，产品样品经过湖南省药品检验研究院检测。而该公司的医用外科口罩生产工艺及标准，符合《医用外科口罩》(YY 0469-2011)和《医用防护口罩技术要求》(GB 19083-2010)等标准。

**湖南频道**

首页 时政要闻 经济民生 科教文卫 社会法治 市州聚焦

当前位置：湖南频道 > 经济民生 > 正文

## 支持疫情防控 又一家“湘字号”口罩厂即将投产

来源：红网 作者：吴媛媛 郭微仙 编辑：肖丹 2020-03-09 22:04:21

时代新人说 我和祖国共成长

通道县委统战部召开脱贫攻坚回头看督查工作动员会

湖南·新闻资讯 > 正文

道县董路村：“黄玫瑰”两手抓

## 支持疫情防控 又一家“湘字号”口罩厂即将投产

2020年03月10日 10:04 来源：红网 0人参与 0评论

相关文章

「你有多美」：在临时急救图

红网时刻3月9日讯（通讯员 吴媛媛 记者 郭微仙）受新冠肺炎疫情影响，全国口罩面临供不应求的局面。为支持疫情防控，近日，又一家“湘字号”口罩厂积极响应号召，即将全面投产。

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JNEYL

## What kind of face mask should we use?

### Ordinary veil face mask

Can block 30% of bacteria and cannot prevent infection

### Medical surgical face mask

Can block 70% of bacteria, can be worn without contact with patients.

### Medical protective mask

N95 mask can block 95% of bacteria

## The correct steps to wear a mask:

1 Make sure that the end of the mask with the metal strip is facing up, and hang the rope at both ends on your ears.

1

2 Cover your nose, mouth, and chin with a protective mask, with the nose clip on top, and close to the face.

2

3 Put your fingertips on the metal nose clip to move and press from the middle position to both sides to ensure the tightness of the mask.

3



Avoid crowds



Regular hand washing

## Standard seven-step hand washing



1、Palms facing each other, fingers rub together.



2、Place your palm against the back of your other palm, rub your fingers against each other, and swap.



3、With palms facing each other, hands rubbing against each other along fingers.



4、The fingers of both hands are interlocked and rubbed together.



5、Hold the thumb of one hand and rub the thumb, and then exchange.



6、Place the tips of five fingers close together in the palm of the other hand, rotate and rub, then swap.



7、Spiral scrub the wrists alternately.