



Certificate of Conformity

NO.: 10065603

This certifies that:

Applicant : FUJIAN JIANJIE MEDICAL DEVICES CO.,LTD
Address : No.58 Xihuang Village, Hushi Industrial Park, Xiuyu District
Putian, FUJIAN, 351100, CHINA
Manufacturer : FUJIAN JIANJIE MEDICAL DEVICES CO.,LTD
Address : No.58 Xihuang Village, Hushi Industrial Park, Xiuyu District
Putian, FUJIAN, 351100, CHINA
Device Listing : D381802 (Respirator, surgical)
EUT : Disposable Protective Mask, N95/KN95 Mask
Models : Disposable Protective Mask, N95/KN95 Mask
Test Standard : Food and Drug Administration Regulation

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, such registration having been verified as effective by Shenzhen Monlka Technology Co.,Ltd.as of the date hereof, and Shenzhen Monlka Technology Co.,Ltd will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2020. Registration information can also be found on the FDA website, it can be found by enter the company name, registration number, administrator number, product model, etc. The website is

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>



Shenzhen MONLKA Technology Co.,Ltd
Building A - B ,Baoshi Science & Technology Park, Baoshi Road, Shiyan Street Bao'an District, Shenzhen, Guangdong, China
www.monlka.cn Tel:0755-23345400





Certificate

ICR Polska/CE/V/01RE579

Name and address of certificate owner: Fujian Jianjie Medical Devices Co.,Ltd
No.58 Xihuang Village, Hushi Industrial Park, Xiuyu District, Putian City Fujian Province China

Name and address of manufacturer: Fujian Jianjie Medical Devices Co.,Ltd
No.58 Xihuang Village, Hushi Industrial Park, Xiuyu District, Putian City Fujian Province China

Product name: Disposable protective mask

Product types: Disposable face masks for civilian use N95 KN95

Product trademark: N/A

- This certificate confirms that the product meets the requirements of the following standard
- The conformity was demonstrated based on following standard(s) listed by European Commission as harmonized with **Regulation 2016/425**

EN 149:2001+A1:2009

The certification has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report(s) No.: MNK20200320359R
Test conducted by: Shenzhen MONLKA Technology Co.,Ltd

Certificate issue date: 01.04.2020

Expiration date: 31.03.2025

NOTE:

- This certificate refers to the above mentioned product and its conformity in regards of above mentioned standard(s) was proven on test sample
- This certificate does not imply meeting all essential requirements, assessment of the series-production or any other restricted Notified Bodies conformity assessment procedure appropriate for the product
- This certificate holder shall use this certificate in connection to declaration of conformity and technical data relevant for the product the certificate was issued

Certificate modifications: n/a



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

Director: Rafal Kalinowski

Warsaw, 01. 04. 2020





产品名称：一次性防护口罩
(非医用)

产品规格：中号

数 量：50个

生产日期：2020.04.16

有 效 期：2年

执行标准 GB/T32610-2016

生产地址：福建莆田秀屿区笏石工业园

福建省健洁医疗器械有限公司

一次性防护口罩外包装参数

1. 外包装纸盒尺寸：长20cm宽10.5cm高8cm
2. 每盒个数：50个（独立包装）
3. 外箱尺寸：长55cm宽42cm高35cm
4. 每盒克重：15.5 克
5. 整箱个数：2500个（纸盒未包装）
6. 每箱重量：9.7KG
7. 整箱个数：40盒/2000个（纸盒包装好）
8. 每箱重量：7.95 KG
9. 说明书见包装盒





180011112242



(2018) 国认监认字 (244) 号



中国认可
国际互认
检测
TESTING
CNAS L6780

检验报告

TEST REPORT



扫一扫关注我们



扫一扫查询真伪



报告编号

REPORT NO.

国纺委字第 W202008737 号

产品名称

NAME OF SAMPLE

一次性防护口罩

委托单位

CUSTOMER

福建省健活医疗器械有限公司

检验类别

TEST CATEGORY

委托检验

浙江省轻工业品质量检验研究院

(浙江省纺织测试研究院)

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心(浙江)


National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心（浙江）

检验报告

国纺委字第 W202008737 号

第 1 页 共 3 页

委托单位名称 Name of Customer	福建 健洁医疗器械有限公司	地址 Address	福建省莆田市秀屿区笏石镇西田村西黄 58 号
生产单位 Manufacturer		地址 Address	---
样品信息 Sample information	样品名称 Name of sample: 一次性防护口罩 样品特性 Characteristics: 蓝色 商标 Trademark: --- 规格/型号 Specification/model: --- 等级 Level: --- 安全技术类别 Category of safety specification: 样品款号/货号 Art. No.: ---		
以上为顾客信息 (Above-mentioned information by Customer-supplier)			
送检方式 The send way of sample	自送	样品数量 Sample quantity	2 只
送检日期 Receiving Date of Sample	2020-04-21	检测类别 Test Category	委托检验
判定依据 Rating Requirements	GB/T 32610-2016		
检测结论/Test Summary: 实测结果详见附页。			
 (检验报告专用章) Seal 批准日期/Date of Approval: 2020-04-22			
备注 Remarks	1、样品标识未标注防护效果级别，按最低标准要求 D 级判定。 2、样品未经预处理，数据供参考。		

签发:
Approved by

俞杰

检验合格

检验报告

国纺委字第 W202008737 号

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序号	检测项目	检测方法	单位	标准要求 (D级)	实测值	单项评价	结果备注	
1	过滤效率(盐性介质)	GB/T 32610-2016 附录 A	%	≥ 90	96.8	符合	---	
2	防护效果	GB/T 32610-2016 附录 B	%	≥ 65	69.6	符合	---	
3	呼吸阻力	GB/T 32610-2016	吸气阻力	Pa	≤ 175	52	符合	---
			呼气阻力	Pa	≤ 145	41		
4	外观质量	GB/T 32610-2016 6.1	—	符合 GB/T32610-2016 标准要求	10 个口罩均外观质量符合标准	符合	---	
5	口罩下方视野	GB 2820-2009 6.8	°	≥ 60	75	符合	---	

检验报告

国纺委字第 W202008737 号

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样品图片



—以下空白—

禁止用于其他商业用途



声明

- 一、本机构保证检测的公正性、独立性和诚实性，对检测结果负责，对委托方所提供的检测样品保密和保护所有权。
- 二、本报告无签发人员签字或未加盖本机构红色检验检测专用章无效。
- 三、报告涂改无效。复印件重新加盖本机构红色检验检测专用章无效。
- 四、本报告的检测数据和结果只对送检样品负责。
- 五、本报告各项均为报告不可分割之部分，使用者单独抽出某些页导致误解或用于其它用途及由此造成的后果，本机构不负相应的法律责任。
- 六、委托方若对本报告有异议，应及时向本机构提出。政府行政管理部门下达的指令性任务，被检方对检验结果有异议时，应按政府行政管理部门文件规定及国家相关法律、法规规定进行。

DECLARATION

1. Our organization guarantees impartiality, independence, and honesty of inspection, and is responsible for the results of inspection, keeping the samples supplied by the entrusting party confidential and at the same time protecting the ownership of the samples supplied.
2. The test report will be deemed invalid without signatures of the inspector/reviewer and authorized personnel, and the red special inspection stamp of our organization.
3. The test report will be invalid if it is altered. Copies of the report are invalid without the red special inspection stamp of our organization.
4. The test results shown in this report are applicable only to the samples provided by customers.
5. All the pages of the report are integral parts of the report. Our organization will not be responsible for any misunderstanding or other results caused by using separate page(s) of the report.
6. If there is any dissent of the report, the entrusting party shall notify our organization timely, or the mandatory inspection given by governmental administration departments, and dissent about the sample being tested or test results on the report should be dealt with in accordance with national regulations.

浙江省轻工业产品质量检验研究院及附设的检验中心

The Affiliated Inspection Centers

浙江省轻工业产品质量检验研究院

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心(浙江)

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

地址: 浙江省杭州市干将路300号6号楼

Address: Building No.6, 300 Xiangsha Road, Hangzhou, Zhejiang

联系电话: 0571-8122669

Telephone: 0571-8122669

E-Mail: 113730794@qq.com

国家家具产品质量监督检验中心(浙江)

National Center for Quality Supervision Inspection of Furniture(Zhejiang)

浙江省室内安全及家具产品质量检验中心

Zhejiang Center of Quality Test for Indoor Safety and Furniture Products

地址: 浙江省杭州市余杭区良渚街道经一路1号良渚大学科技园4号楼

Address: Building 4 LiangZhu University Science and Technology Park, No.1, JingYi Rd, Yuhang District, Hangzhou, Zhejiang

联系电话: 0571-89009556

Telephone: 0571-89009556

E-Mail: 2047699564@qq.com

浙江省轻工及五金产品质量检验中心

Zhejiang Center of Quality Test for Light Industry and Hardware Products

浙江省体育用品质量检验中心

Zhejiang Center of Quality Test for Sports Products

地址: 浙江省杭州市西湖区天目山路222号3号楼

浙江省杭州市余杭区良渚街道经一路1号良渚大学科技园3号楼

Address: No.222 Tiannmushan Rd., Hangzhou, Zhejiang

Building 3 LiangZhu University Science and Technology Park, No.1 JingYi Rd., Hangzhou, Zhejiang

联系电话: 0571-89001107

Telephone: 0571-89001107

E-Mail: wujtest@126.com

国家锁具产品质量监督检验中心(浙江)

National Center for Quality Supervision Inspection of Lock(Zhejiang)

浙江省锁具产品质量检验中心

Zhejiang Center of Quality Test for Lock Products

地址: 浙江省杭州市塘苗路24号

Address: No. 24 Tangmiao Rd., Hangzhou, Zhejiang

联系电话: 0571-85027738

Telephone: 0571-85027738

E-Mail: Locktest@126.com

网上业务受理/报告查询: <http://www.zjtjtj.cn:807>

Online Business-Reception/Report Inquires: <http://www.zjtjtj.cn:807>

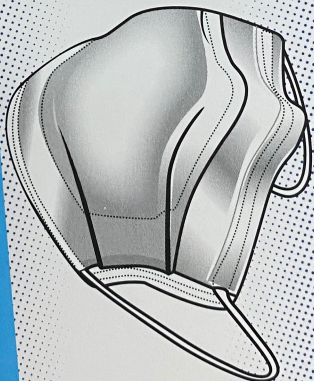
投诉电话: 0571-81023552

Complaint Tel: 0571-81023552



DISPOSABLE FACE MASK

Take Care of Personal & Public Health



NON-MEDICAL

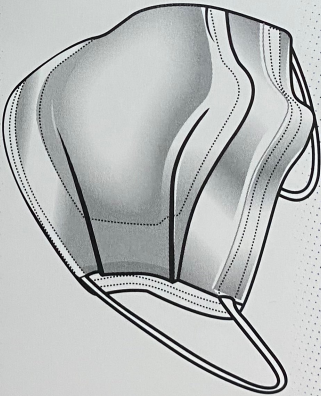
50
PCS



DISPOSABLE FACE MASK

Take Care of Personal & Public Health

NON-MEDICAL

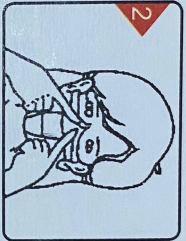


50
PCS

[Instructions]



Ear strap on
both ears



Adjust the
bridge of nose



Unfold the
folding part

[Matters needing attention]

1. This product is disposable and cannot be cleaned and reused.
2. The mask should be kept as flat as possible after use, and the nasal strip above the mask should not be folded frequently to extend the use time.
3. It is not recommended to wear when the air is not circulating, breathing is not smooth or sleeping.
4. Children under three years old are not recommended because of their low vital capacity.

[Date of manufacture] See inner packing

[Quality guarantee period] Two years

[Manufacturer] Fujian Jianjie Medical Devices Co., Ltd

[Production address] Hushi Industrial Park, Hushi Town, Xiyu District, Putian, Fujian, China.

[Execute standard] GB/T32610-2016

QUALITY CERTIFICATE

产品合格证

NON-MEDICAL
非医用

产品名称: Product Name: 一次性防护口罩
(Disposable Protective Mask)

产品型号: Model NO: JJ01

规格Size: 17.5*9.5CM±0.5cm

数量Quantity: 50个/袋 (50PCS)

材质: 无纺布60%, 熔喷布30%, 尼龙绳5%, 铝条5%

Material: Non-woven 60%, Melt-Blown Fabric
30%, nylon Cord 5%, Aluminium Strip 5%

执行标准: Testing Standard: GB/T 32610-2016

有效期: Expiration Date

2年 (储存温度 20°C-38°C, 储存湿度 < 80%, 避光环境下)

2 Year (Storage Temperature 20°C-38°C, Storage
Humidity < 80%, Away From Light, In dark environment)

制造商: 福建省健洁医疗器械有限公司

Manufacturer: Fujian Jianjie Medical Devices Co., Ltd

地址: 福建莆田笏石工业园

Production Address: Hushi Industrial Park
Hushi Town, Xiuyu District Putian Fujian China

Batch No: 生产批号: 202009G

Production Date 生产日期: 2020年9月1日

SPECIFICATIONS:

51.5X38.5X32CM

PLO32

制造商：福建省健洁医疗器械有限公司

Manufacturer: Fujian Jianjie Medical Devices Co.,Ltd



**NO TURN
UPSIDE DOWN**



HANDLE WITH CARE



NO RAIN



CUT ATTENTION



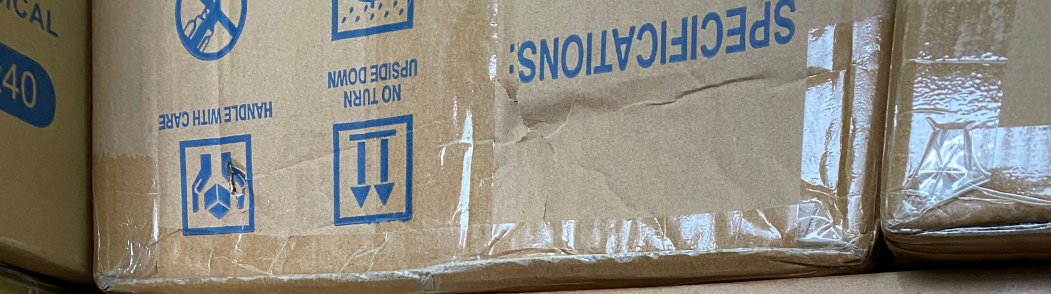
**DISPOSABLE
PROTECTIVE
MASK**

NON MEDICAL



**Filter Layer
Submicron Filtration
Dust Prevention**

**Non-Woven Lay
Hypoallergenic
Ultra Soft Liner**



DISPOSABLE PROTECTIVE MASK

NON MEDICAL

50 pcs. x40

