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营业执照

(副本) 副本编号: 1-1

名称 福建省健洁医疗器械有限公司

注册资本 壹仟万圆整

类型 有限责任公司

成立日期 2020年03月04日

法定代表人 郭建展

营业期限 2020年03月04日 至 长期

经营范围 医用防护口罩生产；非医用防护口罩生产；其他未列明批发业；其他未列明零售业；其他未列明产品制造；化妆品制造；其他日用化学产品制造（不含危险化学品及易制毒化学品）；日用塑料制品制造；日用化工专用设备制造；其他日用品生产专用设备制造；日用及医用机械制品制造；医疗诊断、监护及治疗设备制造；医疗实验室及医用消毒设备和器具制造；机械治疗及病房护理设备制造。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

住所 福建省莆田市秀屿区笏石镇西黄村西黄58号（笏石工业园区）

登记机关



2020年 3月 4日

国家企业信用信息公示系统网址: <http://www.gsxt.gov.cn>

市场主体应当于每年1月1日至6月30日通过
国家企业信用信息公示系统报送公示年度报告

国家市场监督管理总局监制



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

A handwritten signature in blue ink, appearing to read "Rafał Kalinowski".

Director: Rafał Kalinowski

Warsaw, 01. 04. 2020





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, Shiyuan Street Baoan District, Shenzhen, Guangdong, China
www.monlka.cn Tel:0755-23345400







产品名称：KN95防护口罩(非医用)

产品规格：中号

数量：10个

生产日期：20200420

有效期：2年

执行标准 GB2626-2006

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



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



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报告编号

REPORT NO.

国纺委字第 V/202008754 号

产品名称

NAME OF SAMPLE

KN95 防护口罩

委托单位

CUSTOMER

福建省健洁医疗器械有限公司

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)

浙江省轻工业产品质量检验研究院
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 W202008754 号

第 1 页 共 3 页

委托单位名称 Name of Customer	福建省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: KN95 防护口罩 样品特性 Characteristics: 白色 商标 trademark: --- 规格/型号 Specification/model: KN95 等级 Lev 1: KN95 安全技术类别 Category of safety specification: --- 样品款号/货号 Art. No.: ---		
以上为客供信息 (Above-mentioned information by Customer-supplied)			
来样方式 The sent way of sample	自送	样品数量 Sample quantity	20 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 2626-2006		
检测结论/Test Summary: 实测结果详见附页。  检验报告专用章 Test Seal 批准日期/Date of Approval: 2020-04-22			
备注 Remarks	样品未经预处理, 数据供参考。		

签发:
Approved by

曹丽勤

检验报告

国纺委字第 W202008754 号

第 2 页 共 3 页

序号	检测项目	检测方法	单位	标准要求 (KN95)	实测值	单项评价	结果备注
1	过滤效率 (盐性介质)	GB 2626-2006 6.3	%	≥ 95.0	99.2	符合	---
2	呼吸阻力	吸气阻力	Pa	≤ 350	121	符合	---
		呼气阻力	Pa	≤ 250	111		
3	外观检查	GB 2626-2006 6.1 6.2	---	符合 GB2626-2006 标准要求	2个口罩的外 观质量符合标 准要求	符合	---
4	口罩下方视野	GB 2390-2009 6.8	°	≥ 60	79	符合	---
5	头带	GB 2626-2006 6.11	---	$\geq 10N$, 保持 10s	未出现断裂和 滑脱现象	符合	---

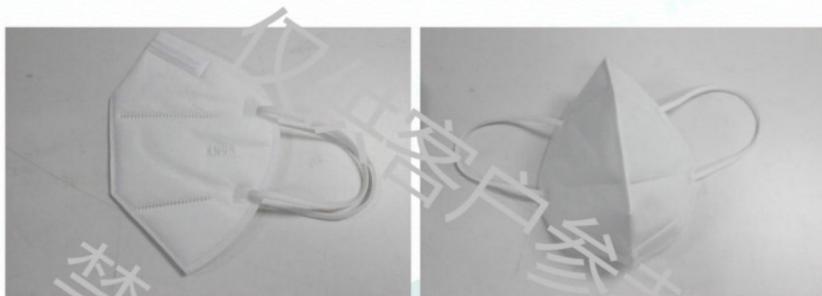


检验报告

国纺委字第 W202008754 号

第 3 页 共 3 页

样品图片



—以下空白—



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。复印件未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仅对送检样品负责。
- 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 signature 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 promptly. For 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：浙江省杭州市江干区下沙路300号3号楼

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

联系电话：0571-85122669

Telephone: 0571-85122669

E-Mail: 1137907994@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 Tianmushan 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: wulect@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.zjtj.cn:807>

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

投诉电话：0571-85023552

Complaint Tel: 0571-85023552





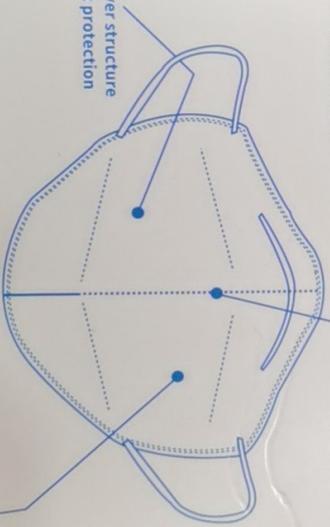
Disposable Mask For Civil Use (NON-Medical)

GB2626-2006

Filtration efficiency is $\geq 95\%$ 

COMFORTABLE WEAR

Customized facial design, 3D stereo tailoring
good tightness and breathability



10 pieces

Filtration efficiency is $\geq 95\%$

[product name] Protective Mask (NON-MEDICAL)

[product specification] 140mm*50mm*140mm

[execution standard] GB2626-2006 KN95

[product structure and composition]

consists of mask body, plastic nose strip and mask belt. The mask body consists of four layers of inner and outer layers of spun-bonded non-woven fabric, intermediate layers of fusion-sprayed non-woven fabric and electrostatic cotton.

[production date] see the packaging code

[validity] 24 months

[Manufacturer] Fujian Jianjie Medical Devices Co., Ltd

[Production Address] Hushi Industrial Park, Hushi Town, Xiuyu District, Putian, Fujian, China.

[Storage conditions]

Avoid direct sunlight, avoid high temperature and humid environment;

[notes]

Disposable products, do not use twice, only for civil use.

[scope of application]

Suitable for protection against all non-oily kinds of particulate matter.

[method of use]

1. Face the face mask without the nose clip, hold the two ear bands by two hands, keep the nose clip above the mask.
2. Put on the mask, put your jaw inside the mask, pull the ear bands behind ears.
3. Adjust the mask to a comfortable position and make it fit your cheek.
4. Press the nose clip with your index and middle fingers from both hands, till the nose clip fit your nose.
5. Do the conduct air tightness test.



但无冠状病毒
牙利流
首 1 EVIG 0%
HIDD EL.
KOL

聚焦国际
2020年2月14日(星期四)

本地新闻 LOCAL NEWS

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产品合格证

Description: Protect
产品名称: KN95防护口罩
Item NO. 型号: KN95
SPEC 规格: 10.5x15.5cm
Quantity 数量: 10PCS
Material: 42.8% Non-Woven Cloth,
28.6% Melt Blown Cloth, 28.6% Cotton Filter
材质: 42.8%无纺布, 28.6%熔喷布, 28.6%热风棉
Execution Standard(CN)中国执行标准:
GB2626-2006
Inspector 检验员: 01
Expiry Date 有效期: 2 Years
Manufacturer: Fujian Jianjie Medical Devices Co., Ltd
制造商: 福建省健洁医疗器械有限公司
Production Address: Hushi Industrial Park,
Hushi Town, Xiuyi District, Putian, Fujian, China.
地址: 福建省莆田笏石工业园
Batch No: 生产批号: 202005G
Production Date 生产日期: 2020年5月4日