



Disposable Protective

mask

一次性防护口罩



2020



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01



企业资质

Enterprise qualification

02



产品相关/认证

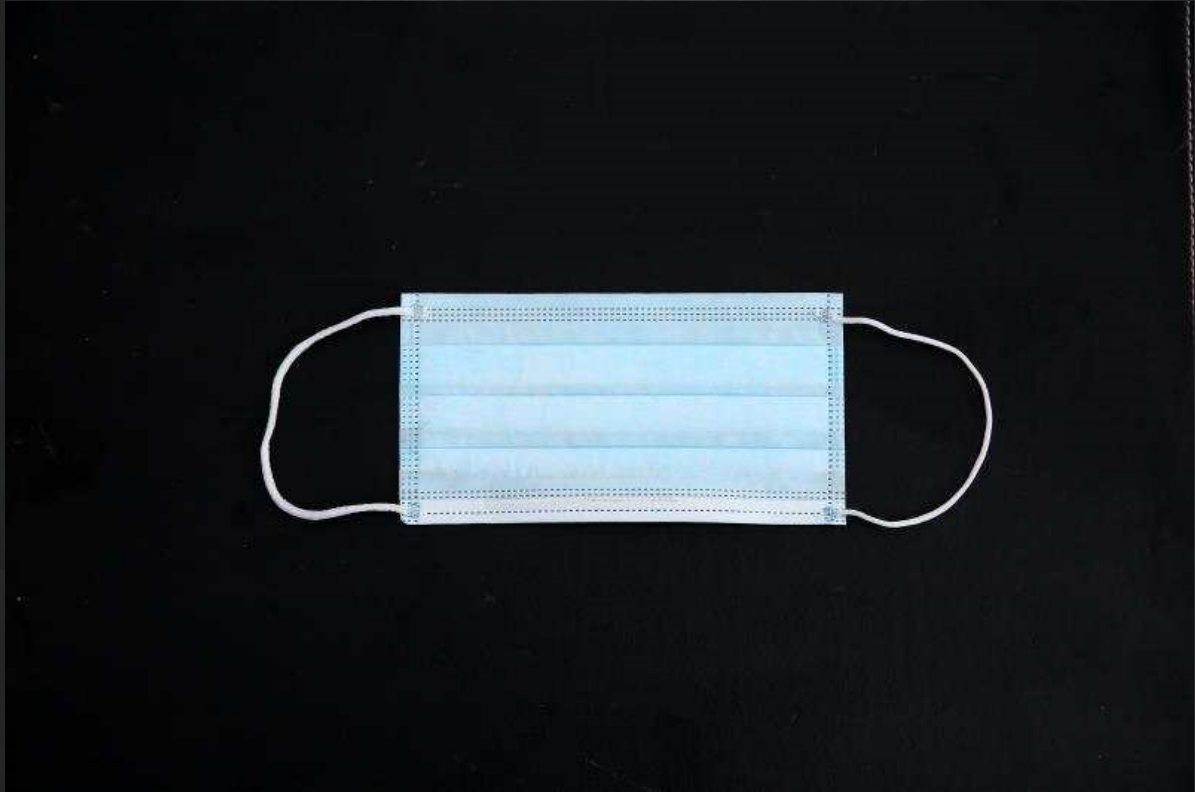
Product Correlation



Product Correlation

产品相关

Product Correlation



Product Certification of Conformity	
Product Name	Protective Mask for daily use
Model Specification	17.5*9.5CM
Quantity	20
<u>Inspector</u>	02
Protection Level	D级
raw materials	Interior Layer: 100% Polypropylene Fiber (Non-woven Fabric) Exterior Layer: 100% Polypropylene Fiber (Waterproof Non-woven Fabric) Filtering Layer: 100% Polypropylene (Meltblown-Filtering Material)
Implementation Standard	Production Guidance for emergency-Protective Civilian Facemasks in Zhejiang Province (Interim)
Lot Number	20200319
Production Date	March 19th,2020
Validity Term	A year

Wenzhou Junchang Medical Equipment Co. , Ltd.
Production address : Phase II, Shoe Capital, Lucheng District, Wenzhou, Zhejiang, China
telephone : 0577-28888369
Place of production : Made in China

CERTIFICATE

Certificate Number **UCN** : **802730433111**
Job : J29243
Date of Issue : 2020-03-18
Certificate valid up to : 2024-03-17

Brand Name : See Label
Type : Disposable Mask
Model N : ear hanging type ,flat shape, duck bill shape, arch shape, folding type

Manufacturer : Wenzhou Junchang Medical Equipment CO., Ltd
Address : 2ND FLOOR WORKSHOP NO.2 AREA SHOES CAPTIAL L.2 FENGMEN TOWN
LUCHEG DISTRICT,WENZHOU CITY ZHEJIANG CHINA


Standard Used : EN 14683:2005

Conclusion :

After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .

The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✓ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : TMZJ20031122168	✓ OK
Presence of  symbol in the product label.	✓ OK
Presence of instruction manual	✓ OK
Use of valid Harmonized standard in the declaration of conformity	✓ OK
Presence of product description in the technical construction file	✓ OK

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Massimiliano Bertoldi
General Manager – CELAB


www.celab.com



CERTIFICATE OF FDA REGISTRATION

Certification No.: CTCSD2020272

Dear Official Correspondent:

This document provides notification of the registration number assigned to your establishment:

Establishment: **WENZHOU JUNCHANG MEDICAL EQUIPMENT CO., LTD.**
 Address: **2ND FLOOR WORKSHOP NO.2 AREA SHOES CAPTIAL L.2**
FENGMEN TOWN LUCHENG DISTRICT
Wenzhou, Zhejiang, 325000, CHINA

Owner/operator NO.: **10062858**

Listing Number	Premarket Submission Number	Product Code(s)	Device Name	Activities
D374583	EXEMPT	KHA	MASK, SCAVENGING	Manufacturer

Helen Kan

General Manager
 CTC REGISTRATION LLC
 Email: ctc-086@hotmail.com
 Web: www.ctc-086.com



Validity: Dec.31,2020

Conclusion:

This certificate makes no other representations or warranties, nor does it make any representations and warranties to any person or entity other than the named certificate holder. CTC assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. CTC is not affiliated with the U.S. Food and Drug Administration.



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中国合格评定
国家认可委员会
CNAS

检验报告

TEST REPORT



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报告编号

REPORT NO.

国纺委字第 YJ202000582 号

产品名称

NAME OF SAMPLE

民用口罩

委托单位

CUSTOMER

温州市俊昌医疗器材有限公司

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 YJ202000582 号

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委托单位名称 Name of Customer	温州市俊昌医疗器械有限责任公司		地址 Address	
生产单位 Manufacturer	---		地址 Address	
样品信息 Sample information	样品名称 Name of sample: 民用口罩 样品特性 Characteristics: 蓝色 商标 Trademark: --- 规格/号型 Specification/model: --- 等级 Level: --- 安全技术类别 Category of safety specification: --- 样品款号/货号 Art. No.: ---			
以上为客供信息 (Above-mentioned information by the client supplied)				
来样方式 The sent way of sample	快递	样品数量 Sample quantity	20 只	
送检日期 Receiving Date of Sample	2020-02-27	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。				
		  Seal 批准日期/Date of Approval: 2020-02-27		
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。			

签发:
Approved by

张雪芳

温州市俊昌医疗器械有限公司

检验报告

国纺委字第 YJ202000582 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	呼吸阻力	GB/T 32610-2016	Pa	≤ 175	40.1	符合	—
	呼气阻力		Pa	≤ 145	42.1		
2	过滤效率	GB/T 32610-2016 附录 A	%	≥ 90		符合	—
3	防护效果	GB/T 32610-2016 附录 B	%	≥ 6	69.4	符合	—



检验报告

国纺委字第 YJ202000582 号

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样品照片



—以下空白—

郑州市俊昌医疗器械有限公司
用章



