



义乌市荣达 医疗器械有限公司

Rong Da, Yiwu City Medical Instrument Co., Ltd.



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义乌市荣达医疗器械有限公司
Rong Da, Yiwu City Medical Instrument Co., Ltd.

简介



义乌市荣达医疗器械有限公司位于浙江省义乌市，是一家以生产高端一次性平面无纺布口罩为主的专业厂家，及研发、外贸、电子商务为一体的规范化企业。

公司拥有按GMP标准建造的洁净生产车间,全自动生产线,有生产设备80台,员工160人。

公司以质量第一，信誉至上为宗旨，即使在时间紧，任务重的情况下，仍能保证质量如期交货，是同行业中实力强，信誉高，经营灵活的企业。公司愿与各国从事此项产品的客户以及外贸公司的友人真诚合作，我们力求做到最好，成为客户的忠实伙伴。

义乌市荣达医疗器械有限公司
Rong Da, Yiwu City Medical Instrument Co., Ltd.

生产资质

统一社会信用代码 91330782MA2HR4EX3H (1/1)		营业执照 (副本)			
名称	义乌市荣达医疗器械有限责任公司	注册资本	壹佰万元整		
类型	有限责任公司(自然人独资)	成立日期	2020年03月24日		
法定代表人	吴根荣	营业期限	2020年03月24日至长期		
经营范围	许可项目：医用口罩生产(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，具体经营项目以审批结果为准)。一般项目：日用口罩(非医用)生产；医用口罩零售；日用口罩(非医用)销售；医用口罩批发(除依法须经批准的项目外，凭营业执照依法自主开展经营活动)。				
登记机关					
2020		03		24	
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	

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证书

شهادة - Certificat - 증명서 - 證明書 - Сертификат - Certificate

CE 认证

Form QAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 4Q200415M.YRMUO74

Certificate's Holder:

Yiwu Rongda Medical Equipment Co., Ltd.
4 / F, No. 37, Yiyi Road, Yiting Town, Yiwu City, Zhejiang Province

Certification ECM Mark:



Product:
Model(s):
Verification to:

Disposable Face Mask
175 x 95 mm
Standard:
EN 149:2001+A1:2009

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products, RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 07 April 2020

Expiry date: 06 April 2025

Reviewer:
Technical expert
Amanda Payne

Approver:
ECM Service Director
Luca Bedonni



Ente Certificazione Macchine Srl

Via Ca' Bella, 243 - Loc. Castello di Serravalle - 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 ☎ +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

FDA 认证

CERTIFICATE OF FDA

Facility Registration and Device Listing of Medical Device

Yiwu Rongda Medical Equipment Co., Ltd.

Owner/Operator Number: 10070858

Registration/FEI Number: Active, Waiting for Registration Number Assignment

Address: 4/F, No. 37, Yiyi Road, Yiting Town, Yiwu City, Zhejiang Province, 322000, CHINA

has completed the Facility Registration and Device Listing with the US FDA, through

HUMISS INC.

Listing Number	Premarket Submission	Product Code(s)	Device Name(s)	Activities	Models
D393976	Exempt	MSH	Respirator, surgical	Manufacturer	KN95 & Disposable Face Mask

HUMISS INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of calendar year stated above, unless said registration is terminated after issuance of this certificate. HUMISS INC. makes no other representations or warranties, nor does this certificate make any representation or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's product(s) or establishment by the US Food and Drug Administration. HUMISS INC. assumes no liability to any person or entity in connection with foregoing.

The US Food and Drug Administration does not issue a certificate of registrations, nor does the US Food and Drug Administration recognize a certificate of registration. HUMISS INC. is not affiliated with the US Food and Drug Administration.



Certificate No: HU-M-200418025

Issue date: Apr 18, 2020
Expire date: Dec 31, 2020

HUMISS INC.
4345 Pearl East Cir Ste 118, Boulder, CO, 80301, USA
901-720-759-5888

义乌市荣达医疗器械有限公司
Rong Da, Yiwu City Medical Instrument Co., Ltd.

合格证



180011112242



(2019) 国认监认字(204)号



中国认可
国际互认
检测
TESTING
CNAS L6780

检验报告

TEST REPORT



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国纺委字第 W202006811 号

报告编号

REPORT NO.

产品名称

NAME OF SAMPLE

委托单位

CUSTOMER

检验类别

TEST CATEGORY

荣达口罩

义乌市荣达医疗器械有限责任公司

委托检验

浙江省轻工业产品质量检验研究院

(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 W202006811 号

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委托单位名称 Name of Customer	义乌市荣达医疗器械有限责任公司	地址 Address	浙江省义乌市义亭镇同义路37号4楼
生产单位 Manufacturer	义乌市荣达医疗器械有限责任公司	地址 Address	浙江省义乌市义亭镇同义路37号4楼
样品信息 Sample information	样品名称 Name of sample: 荣达口罩 样品特性 Characteristics: 蓝色 商标 Trademark: --- 规格/型号 Specification/model: 175*95 等级 Level: --- 安全技术类别 Category of safety specification: --- 样品款号/货号 Art. No.: ---		
以上为客户信息 (Above-mentioned information by Customer-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	2020-04-15	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: 实测结果详见附件。			
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。 3、生产日期:2020-04-13。		

签发:
Approved by

俞杰

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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	120	符合	---
	呼气阻力		Pa	≤145	95		
2	过滤效率(盐性介质)	GB/T 32610-2016 附录A	%	≥90	98.0	符合	---
3	防护效果	GB/T 32610-2016 附录B	%	≥65	66.8	符合	---

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合格证

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，本机构不承担相应的法律责任。
- 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 is only valid for the tested sample.
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 paget(s) of the report.
6. If there is any dissent of the report, the entrusting party shall notify our organization timely. 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：浙江省杭州市江干区下沙路300号6号楼
Address: Building No.6, 300 XiaSha 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: 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：浙江省杭州市塘栖路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](http://www.zjtj.cn/807)

投诉电话: 0571-85023552
Complaint Tel: 0571-85023552

检验报告

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样品图片



—以下空白—

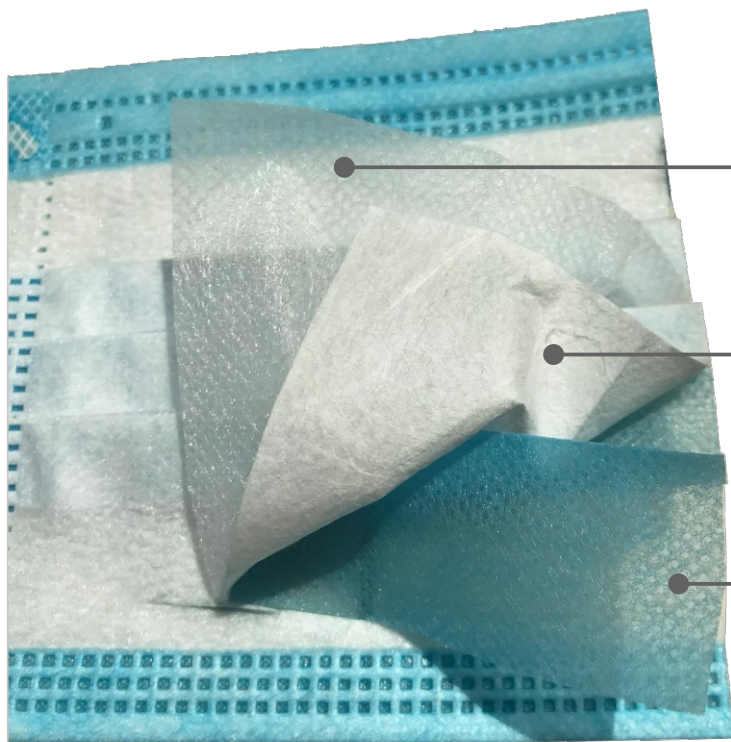


义乌市荣达医疗器械有限公司
Rong Da, Yiwu City Medical Instrument Co., Ltd.

产品实物



产品信息



第三层：亲肤透气抗菌层
Non-woven fabric

第二层：静电熔喷过滤层
Meltbond

第一层：无纺布保护层
Non-woven fabric

包装信息



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包装信息



义乌市荣达医疗器械有限公司

Rong Da, Yiwu City Medical Instrument Co., Ltd.

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