



一次性医用防护口罩介绍

Introduction of Disposable Medical Protective Mask

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特别提示：我司目前具备成熟的一次性口罩生产线，耗材及原料（如高品质熔喷布等）储备充足，原材料紧缺等不确定市场因素对我公司的供货及履约能力影响较小，可以稳定供应高品质防疫产品。

Special note : Our company has a mature disposable mask production line , with sufficient reserves of consumables and raw materials (such as high-quality melt blown cloth, etc.), and uncertain market factors such as shortage of raw materials have little impact on our company's supply and performance ability, which can stably supply high-quality anti epidemic products.



01 公司介绍 ABOUT US



01 公司介绍 ABOUT US



工厂实拍 Our Factory



工厂实拍 Our Factory

中资华夏医药销售有限公司隶属于中资华夏资产管理有限公司，是其全资子公司。中资华夏资产管理有限公司是国务院直属机构-“中国农村小康发展研究中心”(该中心是经中央编制委员会批准、国家事业单位登记管理局登记注册,具有独立法人资格)旗下全资集团公司，注册资本10亿元，旗下有资产管理、投资运营管理、供应链商业贸易、创业孵化器、企业改制重组咨询服务、文化旅游、大健康和康养、高科技研发企业三十多家。其资产管理的领域和经营范围是经金融管理局批准许可予以经营。

China-Funded Huaxia Pharmaceutical Sales Co., Ltd. is a wholly-owned subsidiary of China-Funded Huaxia Asset Management Co., Ltd. ,Which is a directly affiliated institution of the State Council - "China rural well-off development research center" (the center is approved by the Central Compilation Committee and registered by the State Administration of institutional registration, With independent legal person status), it has a wholly-owned group company with a registered capital of 1 billion yuan, and more than 30 enterprises including asset management,investment and operation management, supply chain business trade, business incubator, enterprise restructuring and restructuring consultingservices, cultural tourism, big health and health care, and high-tech R & D enterprises. The field and business scope of its asset management are operated with the approval of the financial authority.

01 公司介绍 ABOUT US



加工车间 Processing Shop



加工车间 Processing Shop

中资华夏医药销售有限公司自成立以来，一直致力于“共促和谐发展，绿色扶贫共赢”理念，始终承诺并致力于参与促进医药销售、产品研发等本领域相关业务，通过不断引进创新医药、开展面向医务工作者专业培训和社会健康意识普及教育等活动，并积极参与支持各项社会公益事业，全力支持我国卫生健康事业的深入发展。

在新型冠状病毒肺炎疫情发生后，公司主动作为号召国内外相关企业及商会，参与到捐赠与防疫物资生产行动中，目前已有具备统一质量管控的防疫物资代工厂三十多家。

Since its establishment, China-funded Huaxia Pharmaceutical Sales Co., Ltd. has been committed to the concept of "promoting harmonious development, green poverty alleviation and win-win", always committed to and committed to participating in the promotion of pharmaceutical sales, product research and development and other related businesses in this field, through the continuous introduction of innovative medicine, carrying out professional training for medical workers and social health awareness education and other activities, and actively participated in the support .We will support the in-depth development of China's health care industry with all kinds of public welfare undertakings.

After the outbreak of novel coronavirus pneumonia, We took the initiative to call on relevant enterprise and chambers of commerce at home and abroad to participate in the production of donations and epidemic prevention materials. At present, there are more than 30 representative plants with unified quality control .



02 产品简介 PRODUCT INTRODUCTION



02 产品简介 PRODUCT INTRODUCTION



我公司生产的一次性医用防护口罩的鼻梁及耳带等细节做工精良、口罩形状比例符合人体工学、佩戴舒适、贴合度高。

The disposable masks produced by our company have excellent details such as nose bridge and ear belt, and the shape proportion of masks is in line with ergonomics, comfortable to wear and high fitting.



拒水无纺布

Water repellent non-woven fabric

阻隔熔喷布

Blocking spray cloth

亲肤无纺布

Skin-friendly non-woven fabric

三层防护 Three layers of protection

外层防水无纺布防飞沫，内层吸收无纺布舒适更干爽，中间医用，BFE \geq 99%，无纺布阻隔病毒与细菌，保护健康

医用级别（灭菌型或非灭菌型） Medical grade (sterilized or non-sterilized)

提供灭菌型医用外科一次性口罩和非灭菌型医用防护一次性口罩两种类型，可分别在无菌和非无菌环境下使用

质量保证 Quality assurance

从原材料、生产加工到质检分装，严格执行相关管理标准，确保产品符合品质标准



03

工厂资质 FACTORY QUALIFICATION



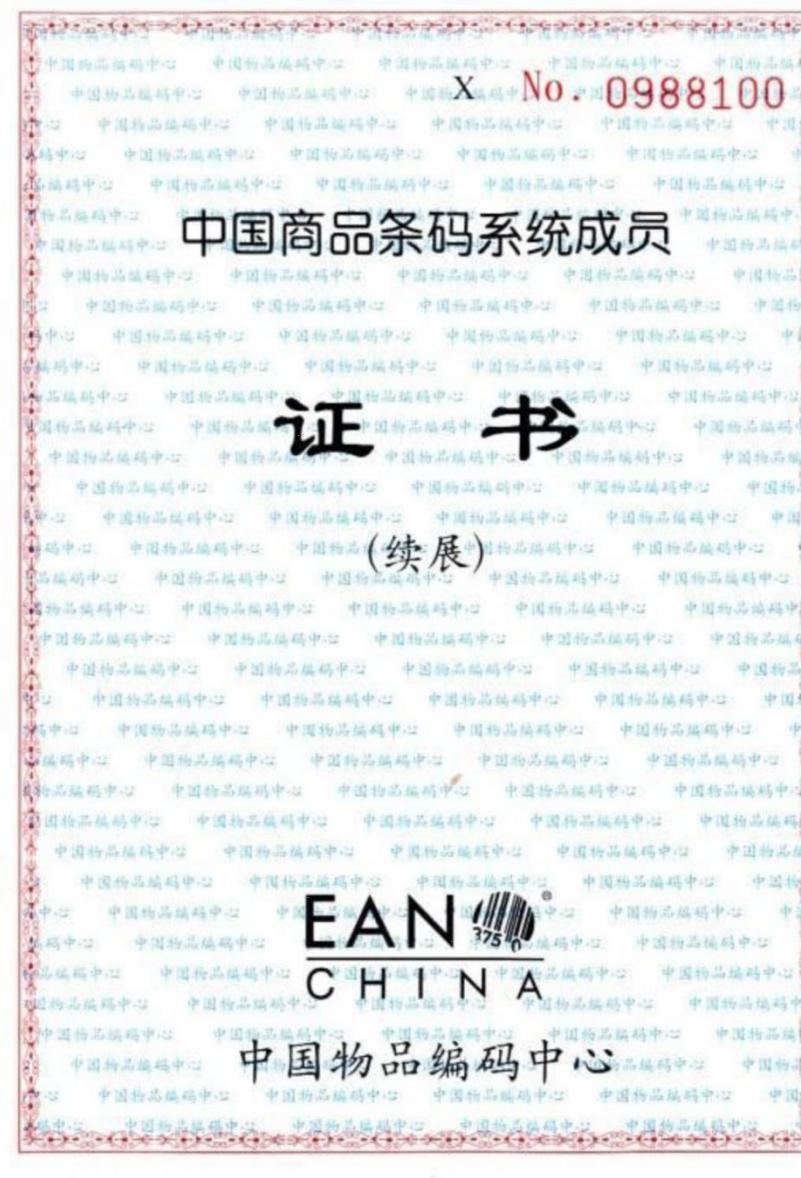
03 工厂资质 FACTORY QUALIFICATION



03 工厂资质 FACTORY QUALIFICATION



03 工厂资质 FACTORY QUALIFICATION



03 工厂资质 FACTORY QUALIFICATION





04 认证报告 CERTIFICATION REPORT



04 认证报告 CERTIFICATION REPORT



CERTIFICATION OF REGISTRATION Fiscal Year 2020

This certifies that:

Sichuan Lezhi Guijun Sanitary Material Co. LTD
The West Gongye Yuanqu of Tianchi Country
Lezhi Ziyang, Sichuan
People Republic of China

has registered with the U.S. Food and Drug Administration Pursuant to section 305 of the United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, such registration having been verified as currently effective on the date here of by Authentic Customs Brokers, Inc.

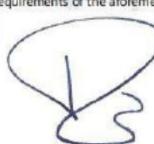
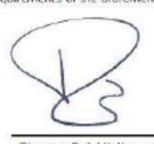
U.S. FDA Registration NO.: 12899404930
Effective Date of Registration: 03/23/2020
Expiration Date: 12/31/2020



This certificate affirms that the above stated facility was registered with the U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002.P.L.107-188, on the date stated above, and makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Authentic Customs Brokers, Inc. assumes no liability to any person or entity in connection with the foregoing. Authentic Customs Broker, Inc. is a private registration agent not affiliated with the U.S. Food and Drug Administration.

Authentic Customs Brokers, Inc.
147-10 181 Street, Unit G
Springfield Gardens, NY 11413
United States
Tel: 347-494-4251
Fax: 347-494-4418

Danny Xu
U.S. Licensed Customs Brokers

International Certification Registrar International Certification Registrar International Certification Registrar		International Certification Registrar International Certification Registrar International Certification Registrar	
 Certificate			
Name and address of certificate owner: Guizhou Miaozetang Biotechnology Co.,Ltd No.18, Jinyuan West Avenue, Economic Development Zone,Kaili City, Qianxiangnan Prefecture, Guizhou Province, China		Name and address of Registered Manufacturer: Guizhou Miaozetang Biotechnology Co.,Ltd No.18, Jinyuan West Avenue, Economic Development Zone,Kaili City, Qianxiangnan Prefecture, Guizhou Province, China	
Name and address of manufacturer: Guizhou Miaozetang Biotechnology Co.,Ltd No.18, Jinyuan West Avenue, Economic Development Zone,Kaili City, Qianxiangnan Prefecture, Guizhou Province, China		Product name: Disposable Medical Mask	
		Product types: Hanging Ear Type:175mm*95mm	
		Product trademark: MIAO ZE TANG	
<p>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</p> <p>EN 149:2001+A1:2009</p> <p>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 CHINA CEPREI (SICHUAN) LABORATORY</p> <p>No. of test reports: 8039022804A2020</p> <p>Certificate issue date: 24.03.2020 Expiration date: 23.03.2025</p> <p>The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3105.</p> <p>This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.</p> <p> Director: Rafal Kalinowski</p> <p>Warsaw, 24. 03. 2020</p> <p>ICR Polska Co. Ltd. ul. Plac Przymierza 6 03-544 Warsaw www.icrpolska.com, e-mail: icrpolska@icrqqa.com</p> <p></p>			
		Product name: Disposable Medical Mask	
		Product type/model: Hanging Ear Type:175mm*95mm	
		Trade mark: MIAO ZE TANG	
<p>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.</p> <p>Relevant EC Directive: Medical Device Directive 93/42/EEC</p> <p>Conformity assessment procedure: EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)</p> <p>Classification: Class I according Rule 1 of Annex IX of Directive 93/42/EEC</p> <p>Applied normative documents: EN 14683:2014</p> <p>Applied Quality Management System: n/a</p> <p>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: • CHINA CEPREI (SICHUAN) LABORATORY</p> <p>No. of test reports: 8039022803A2020</p> <p>Issue date: 24.03.2020 Expiration date: 23.03.2025</p> <p>The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3125.</p> <p>This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.</p> <p> Director: Rafal Kalinowski</p> <p>Warsaw, 24. 03. 2020</p> <p>ICR Polska Co. Ltd. ul. Plac Przymierza 6 03-544 Warsaw www.icrpolska.com, e-mail: icrpolska@icrqqa.com</p> <p></p>			

04 认证报告 CERTIFICATION REPORT

贵州省医疗器械检测中心
检测报告首页

报告编号: WT200421

共2页 第1页

样品名称	一次性使用非无菌口罩		样品编号	WT200421
	送样(√)	抽样()		
商标	/		规格/型号	/
委托方	黔东南州市场监督管理局		检验类别	委托检验
委托方地址	/		产品编号 /批号	20200321
标示生产单位	贵州苗泽堂生物科技有限公司		检样单编号	/
受检单位	/		生产日期	/
送样单位	黔东南州市场监督管理局		样品数量	20个
收样地点	本检测中心		抽样基数	/
抽样日期	/		检测地点	本检测中心实验室
收样日期	2020年3月23日		检测日期	2020年3月23日至 2020年3月23日
检测项目	颗粒过滤效率(PFE)			
检测依据	YY 0469-2011《医用外科口罩》			
检测结论	按 YY 0469-2011《医用外科口罩》对一次性使用非无菌口罩的“颗粒过滤效率(PFE)”项目进行检测，具体检测结果见检测报告。  签发日期: 2020年3月23日			
备注	报告中的“—”表示此项不适用，报告中“/”表示此项空白			

批准: 郑海

审核: 陈刚

检验: 刘晓丹

签名: 郑海

签名: 陈刚

签名: 刘晓丹

04 认证报告 CERTIFICATION REPORT

贵州省医疗器械检测中心

检验报告首页

报告编号: ZC200150

共3页 第1页

样品名称	一次性使用医用口罩		样品编号	ZC200150
	送样(√)	抽样()		
商标	/		规格型号	挂耳式 17.5cm×9.5cm
委托方	黔东南州市场监督管理局		检验类别	注册检验(应急)
委托方地址	/		产品编号/ 批号	20200321
生产单位	贵州苗泽堂生物科技有限公司		抽样单编号	—
受检单位	/		生产日期	/
送样单位	黔东南州市场监督管理局		样品数量	50个
收样地点	本检测中心		抽样基数	—
抽样日期	—		检验地点	本检测中心实验室
收样日期	2020年3月23日		检验日期	2020年3月23日至 2020年3月24日
检验项目	鼻夹、口罩带、细菌过滤效率(BFE)			
检验依据	贵州苗泽堂生物科技有限公司医疗器械产品技术要求《一次性使用医用口罩》			
检验结论	所检项目符合贵州苗泽堂生物科技有限公司医疗器械产品技术要求《一次性使用医用口罩》的要求。 			
备注	报告中的“—”表示此项不适用，报告中“/”表示此项空白。			

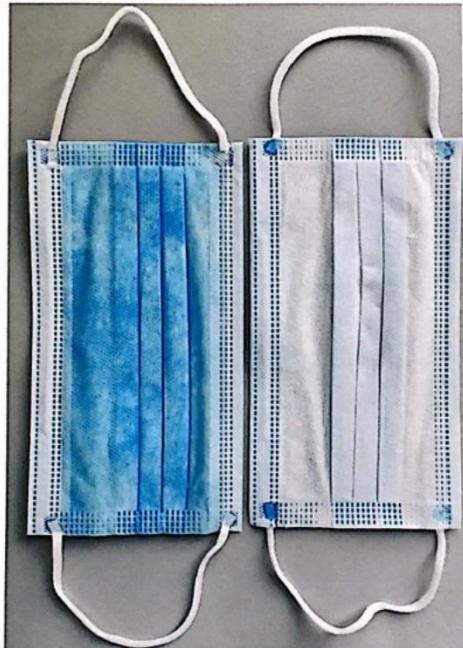


贵州省医疗器械检测中心 检验报告照片页

报告编号: ZC200150

共 3 页 第 3 页

照片和说明



样品描述

样品状态: 完好。

型号规格或其他说明

型号规格: 挂耳式 17.5cm × 9.5cm

医疗器械产品技术要求预评价意见

检验报告编号: ZC200150

共 1 页 第 1 页

一、产品技术要求中性能指标的完整性与适用性; 检验方法是否具有可操作性和可重复性, 是否与检验要求相适应。

产品技术要求中所检项目性能指标基本完整, 性能指标的检验方法具有可操作性和可重复性, 与检验要求相适应。

二、依据现行强制性或推荐性国家标准、行业标准检验的, 所用强制性国家标准、行业标准的完整性, 所用标准与产品的适宜性, 所用条款的适用性。

该产品所检项目所引用推荐性国家标准完整, 所用标准与产品相适宜。

三、如检验内容涉及引用中国药典的相关内容, 其引用的完整性、适宜性和适用性。

无

四、其他需要说明的问题。

无

五、综合评价意见:

经预评价, 对产品技术要求无补充、完善意见。

经预评价, 产品技术要求在以下方面需要进一步补充、完善:

性能指标:

适用国家标准、行业标准:

引用《中华人民共和国药典》内容:

