

3 PLY DISPOSABLE FACE MASK SPECIFICATIONS

Manufacturer	FDA Registration	Certifications	Standards	Protection Level
Dongguan Zmiao Health Technology Co., Ltd.	Owner/Operator #: 10069222 Device Listing for product code QKR	CE Compliant ISO 13485: 2016 Notified Body UKAS 0236	Europe (EN 149-2001 +A1-2009) (Type 1) China (YY/T 0969-2013)	Type I

DESIGNED FOR

- ◆ General public, patients, customers



DESIGNED TO PROVIDE

- ◆ Bacterial Filtration Efficiency Rate (BFE) > 95%
- ◆ A disposable, soft, lightweight, fiberglass-free, and splash resistant protection
- ◆ Protection against large splashes or sprays







Navigating the new supply chain during a pandemic

During times of crisis, such as natural disasters, power outages, or regionalized impacts, a business has an opportunity to enact what is called their “business contingency plan” (BCP). BCP’s should acknowledge how some of these initial concerns will be addressed during times of a fluctuating supply chain:

- Does the **demand** exist for our current products?
- Do we have the **capacity to replenish** our products for **consistent inventory**?
- Do we have **dedicated warehouses** or **transportation** companies that can ensure delivery?
- Can we **distribute** our products in a timely manner?
- Is our **work force** protected?

However, what our world, individual countries, and localized economies are dealing with today is unprecedented. That is why it is important at Restore Robotics to provide our customers with our BCP to show how we differ from other suppliers during the COVID-19 outbreak. We understand that during times when you need protection the most, to have assurances that we can deliver our products to you in a timely manner.

Let’s take a look into our BCP during COVID-19:

Does the demand exist for our current products?

Yes! At Restore, we aim to provide personal protective equipment (PPE) for healthcare personnel and other protective products for the general public’s usage. In 8 weeks, we have provided 76 million pieces of PPE, protective masks, and hand sanitizer directly to American hospitals, retailers, and distributors from our international manufacturing facilities.

Currently, American hospitals and healthcare facilities are experiencing shortages in PPE. How does something like this occur? It can be as simple as a disruption in what is considered the ‘normal’ supply chain. During this pandemic, we have personally observed facets that disrupt ‘normal’ behavior: increased shipping prices, increased quality control checks at international borders holding up material for days, fake PPE trying to pass off as NIOSH-approved, and even ‘middle-men’ brokers offering cash to facilities with already promised buyer inventory. That is why we have entered what we like to call the ‘new supply chain’ pandemic era. In this thinking, we have tried to cut out as many ‘middle’ men as possible. **That’s why at Restore we are involved in every step of the supply chain process of our products, starting from manufacturing to the final delivery at your American business or hospital.**

Do we have the **capacity to replenish** our products for **consistent inventory**?



Yes! We are contracted with different manufacturers in China to receive 100% of the products produced at their factory (or their 'production capacity'). As well, we have ensured that the manufacturers chosen are in full operational capacity to import into the U.S.A. (correct certificates and standardized testing documents required). Each week we also deliver the outer packaging cartons to our trusted manufacturers, cutting out another 'middle' man internationally. Given that one of Restore Robotics partners lives in Hong Kong, we can physically check in on our employees, trusted manufacturers, transportation, and delivery of products to the border without there being a threat of a language-barrier.

Do we have **dedicated warehouses** or **transportation** companies that can ensure delivery?

At Restore, we do not utilize brokers to get our products between warehouses or to the consumer. We do however, use multiple facets of the transportation sector each week, all delivering our products to the U.S.A. at different speeds. Our current modes of international transportation include using privately chartered planes four times a week, UPS shipping, and freight cargo ships. Every two days, we have semi-trucks leaving our international warehouses to deliver products to the various transportation modes, beginning the shipping process to the U.S.A. In this way, we hope to combat recently increased wait times at Customs by utilizing multiple points of entry. And, if and when a situation like this arises, we have inventory already in stock at our American warehouses or in flux to the U.S.A. This approach has given Restore a continuous flow of PPE and hand sanitizer to our customers (76 million pieces in 8 weeks), making it not only into the country safely and under the proper legal regulations, but to your business or hospital quickly after arriving to our American warehouse.

Can we **distribute** our products in a timely manner?

Yes! We own sectors of the transportation and distribution of our products, including ownership of the shipping containers, semi-trucks, and holding warehouses. This significantly cuts pick-up and drop-off wait times for our products to arrive to international border checks and to the final delivery destination in the U.S.A. Our currently owned holding warehouses are located internationally in Hong Kong and Shenzhen, China and domestically in Anaheim, California, and Buford, Suwanee, and Alpharetta, Georgia. As well, we have our own security team guarding the warehouses and shipments to ensure no products are stolen.

Is our **work force** protected?

Yes! Protective face masks are provided for our employees to wear that are not currently working at home. Financially, our work force has not experienced any furloughing of employees, but rather hiring more to help pack and distribute products at our American warehouses. We have 100 employees split between our warehouse in Hong Kong and Shenzhen, China and about 75



employees in our logistical and management teams in the U.S.A. Furthermore, we have work force that live on-site at our international warehouses dedicated to the protection and weekly quality control testing required from our PPE products.

Our Story

What did Jason Li and Clif Parker have in common besides their ZIP codes? Their desire to HELP.

Both Jason and Clif met only through a 'friend-of-a-friend': Jason's current business partner Brad Yen at i-Blason, a multi-million dollar global company supplying top-of-the line phone and tablet cases, knew a friend working at Restore Robotics. Restore, a company responsible for repairing surgical robots, was looking for dependable supply lines coming out of China for personal protective equipment (PPE). Clif Parker, CEO of Restore Robotics, had gotten a phone call from Ardent Health, expressing their dire need for PPE materials for their 31 hospitals. When other clients began to call, the same desperation in their voices pleading for any help, it struck an emotional chord in Clif. "I remember just thinking. How could I possibly make this happen?"

Enter Jason Li and his partner Brad Yen. With their combined beginnings in IT infrastructure and marketing analyses, they started i-Blason in 2011. Using dedicated contracts with manufacturing facilities in China, today the company has grown to supply their products to cities all over the world, from Dubai to New York. With such a massive logistical network in place from their years at i-Blason, Jason and Brad were poised to help bring in PPE to Restore's clients. Especially given that Jason and Brad had already donated millions of pieces of PPE to China's citizens around the Chinese New Year, a time when the COVID-19 outbreak was in full swing.

"It was pretty crazy. We met for about an hour and a half on March 19th with five of us against the walls talking in a room. I knew after meeting Clif, and talking to him for hours on the phone, that I could trust him. And that he could trust me. We haven't even signed a contract." Jason remarked. Four days and ten million dollars later, they started shipping out KN95 respirators, face masks, isolation gowns, and face shields from China's shores. Only ten days in, they had flown over 15 million pieces of PPE to the U.S.A. "Right now, I don't think any privately owned company in the U.S. has been able to ship more than us. We got 40 million pieces into the country over 4 weeks, spread between private jets, cargo boats, and Boeing 747's. We have invested every penny into the inventory needed to provide safety to American workers," Jason uttered over the phone.

Simultaneously, Restore was not only trying to provide PPE to its previous customers, but something more familiar to them: ventilators. Another pleading phone call from a client in New Jersey led Clif to one of the craziest experiences in his life. Three maxed out credit cards, and one private jet at 670 miles/hour, Clif was able to supply an extra inventory of 21 ventilators to a hospital 'hot spot' in less than 12 hours. The next day, receiving a phone call from the Top Executives of the hospital system explaining that he may have just single-handedly saved 19 lives

hit Clif harder than any business transaction he has ever done. “I remember getting off the phone and wandering out to the fire pit stunned. It really changed my whole outlook on this pandemic.”

Clif and Jason are truly an unlikely pair coming together to help a nation combat a fractured global supply chain system’s impact on our healthcare system. Clif and Jason have aided in supplying Americans with PPE when they have needed it most. And they will continue to do so. Because at Restore, they hope to keep any business, small or large, to run under safety standards the public needs at this time.



Unloading ventilators in New Jersey, U.S.A. in March 2020.



Top left: Inventory of Hand Sanitizer during late April. Top Right: The best way to get product over internationally is to sometimes buy out passenger seats on commercial flights! Bottom: Happy to receive product!



Our Certifications and Standards

All FFR or face masks used for medical purposes in the United States must undergo certain regulatory testing requirements per the Food and Drug Administration (FDA). Such regulatory testing's are completed to meet specific performance requirements and physical characteristics in order to guarantee a quality and consistent product. Other countries (i.e. New Zealand, Australia, Japan, China) or regions (Europe) have adopted their own specific testing requirements for FFRs and face masks, and in some cases, international standards (ISO) are agreed upon by leading experts from different nations. However, during a crisis or pandemic when these products become increasingly more scarce to find, other regional standards are adopted in order for continuous flow of product to regions experiencing disruption in supply lines. This was recently observed in the United States, where the FDA has accepted a slightly different quality of standard for N95 facemasks for healthcare personnel dealing on the front lines of the COVID-19 pandemic (<https://www.nytimes.com/2020/04/03/health/coronavirus-n95-kn95-masks.html>). Now, the FDA has approved the use of KN95 or FFP2 masks, which offer similar quality and protection but are more readily available and less costly to manufacture.

- Our company meets the ISO for sector specific application of quality management systems (ISO 13485: 2016) “for providing medical devices and related services that consistently meet customer and applicable regulatory requirements” (<https://www.iso.org/standard/59752.html>; <https://www.iso.org/iso-9001-quality-management.html>).
- We use recognized performance standards from Europe and China to deliver consistent and safe FFRs and face masks to our clients.

Please take a moment to review our official documents.



Dongguan Zmiao Health Technology Co., Ltd.

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

DONGGUAN ZMIAO HEALTH TECHNOLOGY CO.,LTD

**Building 118, No.22 Xinghong Road, Xintaiyang Industrial
City, Lincun, Tangxia Town
Dongguan City, GUANGDONG, 523711, CHINA**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Owner/Operator Number: 10069222

Device Listing#: See annex

Listing No.	Code	Device Name	Proprietary Names	Activities
D390117	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance	Disposable Medical Non-Sterile Mask ZM025 ZM025A	Manufacturer
D402926	MSH	Respirator, surgical	KN95 Protective Mask ZM026	Manufacturer

HRC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. HRC 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. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration.

HRC assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." 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, HRC is not affiliated with the U.S. Food and Drug Administration. Chief engineer

Andy Sun

Issued: May 17, 2020

Expiration Date: December 31, 2020



认证证书

证书编号: 10136358Q

兹证明

东莞市蒸妙健康科技有限公司
东莞市塘厦镇林村新太阳工业城新鸿路 22 号第 118 栋

质量管理体系认证符合标准

ISO9001:2015

质量管理体系适用于

研发、产销: 医疗仪器(第二类医疗器械)、药品、电子产品、五金塑胶; 自动化设备的技术开发、技术咨询、技术转让、技术服务; 实业投资; 股权投资; 房地产开发; 酒店投资; 物业管理; 企业管理咨询; 商务信息咨询; 市场营销策划; 企业形象策划; 展览展示策划; 制作、复制、发行: 广播电视节目[广播剧、电视剧、动画片、专题、专栏(不含时政新闻类)、综艺]; 设计、制作国内外各类广告

发证日期: 2019-12-09

证书有效期至: 2022-12-08

获证组织在证书有效期内每年至少接受一次监督审核, 并将监督审核合格标识粘贴于证书指定位置, 证书方为有效。



签发: *Franco*

12 个月	24 个月
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欧洲认证(香港)有限公司

WWW.CCE-HK.COM



QCC
www.qcc-cn.com

证书编号: 10137240Q

兹证明

东莞市蒸妙健康科技有限公司
中国广东省东莞市塘厦镇林村新太阳工业城新发路 6 号第 82 栋

质量管理体系认证符合标准

ISO13485: 2016

质量管理体系适用于

医疗器械(第二类医疗器械)、药品、电子产品、五金塑胶的研发及销售(不含有资质许可要求的产品)

发证日期: 2017-09-12

到期日: 2020-09-11

本证书的使用和有效性应满足质量管理体系认证规则的要求。获证组织在证书有效期内每年至少接受一次监督审核, 并将监督审核合格标识粘贴于证书指定位置, 证书方为有效。

签发: *Timothy*

意大利质量认证中心



0236



检验检测报告

(电子版)



防伪查询网址: www.gttc.net.cn

防伪码: CSHX-1489-04

共3页 第1页

No:200057887



委托单位	东莞市蒸妙健康科技有限公司 地址: 广东省东莞市塘厦镇新太阳工业城新鸿路22号118栋		
样品信息	一次性医用口罩 20个 商标: zmiao 号型规格: ZM025 17.5*9.5cm		
检验性质	委托检测	样品受理/测试开始日期	2020-04-02
		报告签发日期	2020-04-07
判定依据	YY/T 0969-2013 《一次性使用医用口罩》		
综合检验结论	—		
检验检测结果	检验检测项目	判定依据	判定
	细菌过滤效率	YY/T 0969-2013	符合
	外观[3个]	YY/T 0969-2013	符合
	结构与尺寸[3个]	YY/T 0969-2013	符合
	通气阻力	YY/T 0969-2013	符合
	鼻梁[3个]	YY/T 0969-2013	符合
	口罩带[3个]	YY/T 0969-2013	符合
备注	通气阻力项目暂未获得CNAS认可。 本报告中检验检测项目均在相应标准规定的环境条件下进行(有注明的除外)。 复印件、副本未重新加盖报告书确认章无效。 本报告检验检测地址为广州市番禺区珠江路1号。		



签发: 郭子山 高级工程师

样品图片

(电子版)

No:200057887
共3页 第2页



检验检测报告附页

(电子版)

No:200057887
共3页 第3页

检验检测项目 (计量单位) [样品识别]	测试方法	标准值及允差	检验检测结果	判定	备注
●细菌过滤效率 (%)	YY 0469-2011 附录B 测试菌株: 金黄色葡萄球菌ATCC 6538 测试面积: 40cm ² 气体流速: 28.3L/min 平均颗粒直径: 3.0 μm 阳性质控值: 1.9×10 ³ CFU 阴性质控值: <1CFU	≥95	BFE _a : 96.8 BFE _b : 96.6 BFE _c : 96.5	符合	
●外观[3个]	YY/T 0969-2013 5.1	口罩外观应整洁、形状完好, 表面不得有破损、污渍。	符合要求	符合	
●结构与尺寸 [3个]	YY/T 0969-2013 5.2	口罩佩戴好后, 应能罩住佩戴者的口、鼻至下颌。应符合设计的尺寸, 最大偏差应不超过±5%。	结构: 符合要求 尺寸最大偏差 (%): -3	符合	
●通气阻力 (Pa/cm ²)	YY/T 0969-2013 5.6	≤49	1# 31.8 2# 33.9 3# 29.4	符合	
●鼻梁[3个]	YY/T 0969-2013 5.3	口罩上应配有鼻梁。鼻梁由塑性材料制成。鼻梁长度应不小于8.0cm。	鼻梁: 符合要求 鼻梁长度 (cm): 1# 10.8 2# 10.9 3# 10.8	符合	
●口罩带[3个]	YY/T 0969-2013 5.4	口罩带应佩戴方便。每根口罩带与口罩体连接点处的断裂强度应不小于10N。	符合要求	符合	
备	(本栏空白)				
注					



—本报告结束—



**DECLARATION OF CONFORMITY
ACCORDING TO THE
REGULATION (EU) 2017/745**



File. No.: C200414133C

Manufacturer : DONGGUAN ZMIAO HEALTH TECHNOLOGY CO., LTD
Building 118, No.22 Xinghong Road, Xintaiyang Industrial
City, Lincun, Tangxia Town, Dongguan City, Guangdong
Province, China 523710

Product : Disposable medical non-sterile mask

Model : ZM025, ZM025A

Classification : Class I medical device
According to Annex VIII of Regulation (EU) 2017/745

Date of Manufacture : Mar 2020

**European Authorised
Representitive** : 3A Inno UG(haftungsbeschränkt)
Eisfelder Str. 12, D-96450 Coburg, Germany
Tel: +49 8803 8919981
Email: 3ainnoug@gmail.com

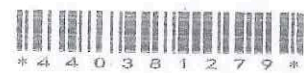
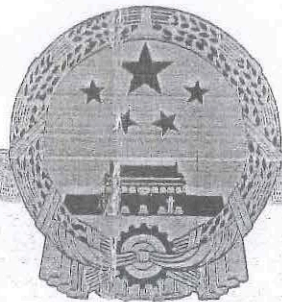
Harmonised Standard : EN 14683:2019
which Comply With Medical face masks. Requirements and test methods
Type I

The manufacturer declares under his sole responsibility that the above product under normal conditions of use and determined by the manufacturers Conditions is secure and all necessary legal conditions and Requirements fulfilled. The product is a medical device that is unique Use is intended and only corresponds to the manufacturer's instructions.

The manufacturer declares that he has taken all necessary measures to ensure that the Conformity of the products placed on the market with the technical documentation and ensure the basic requirements for this type of product.

DONGGUAN ZMIAO HEALTH TECHNOLOGY CO., LTD

ISSUED DATE: 14 APR 2020
EXPIRED DATE: 13 APR 2021



统一社会信用代码
91441900696409700Q

营业执照



扫描二维码登录“
国家企业信用信息
公示系统”了解更
多登记、备案、许
可、监管信息。

名称 东莞市妙特塑料制品有限公司

注册资本 人民币壹佰壹拾万元

类型 有限责任公司(自然人投资或控股)

成立日期 2009年10月20日

法定代表人 曹莉芹

营业期限 长期

经营范围 产销：塑料制品、电子产品、金属制品、智能柜、电动玩具、智能共享储物柜及仪器，家庭用纺织产品，木制玩具及家具、蓝牙遥控、游戏设备及软件；生产、研发、零售：二类医疗器械；商品信息咨询；市场营销策划；企业管理咨询；增值电信业务经营（互联网信息服务）；货物进出口、技术进出口。（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 东莞市塘厦镇林村（新太阳工业城）新贵路5号第50座、8号第57座厂房



登记机关



2019年11月28日

请于每年6月30日前报送年度报告，逾期将受到信用惩戒和处罚。
途径：登录企业信用信息公示系统，或“东莞市场监管”微信公众号。

中华人民共和国医疗器械注册证

注册证编号：粤械注准 20192200745

注册人名称	东莞市妙特塑料制品有限公司
注册人住所	东莞市塘厦镇林村（新太阳工业城）新贵路5号第50座厂房
生产地址	东莞市塘厦镇林村（新太阳工业城）新贵路5号第50座厂房
产品名称	远红外熏蒸仪
型号、规格	SPV-II
结构及组成	由远红外治疗子系统、足疗子系统、蒸汽浴疗子系统（含蒸汽引流瓶）组成。
适用范围	适用于中药熏蒸治疗。
附件	产品技术要求。
其他内容	无
备注	原产品注册证号：粤食药监械（准）字2014第2261082号。

审批部门：广东省药品监督管理局

批准日期：2019年07月01日

有效期至：2024年06月30日



医疗器械生产许可证

许可证编号：粤食药监械生产许20183183号

企业名称：东莞市妙特塑料制品有限公司

生产地址：东莞市塘厦镇林村（新太阳工业城）新贵路5号
第50座厂房

法定代表人：袁春洋

生产范围：II类6826物理治疗及康复设备。

企业负责人：曾铁彬

住所：东莞市塘厦镇林村（新太阳工业城）新贵路5号
第50座厂房

发证部门：广东省食品药品监督管理局

有效期限：至 2023 年 07 月 08 日

发证日期：2018 年 07 月 09 日

