



# Medical Isolated Mask

⋮

有限公司

深圳市九派通供应链有限公司

深圳市

# Medical Isolated Mask

## Feature:

Safe/Air-permeable/Comfortable

Product qualification Certified by  
FDA and CE

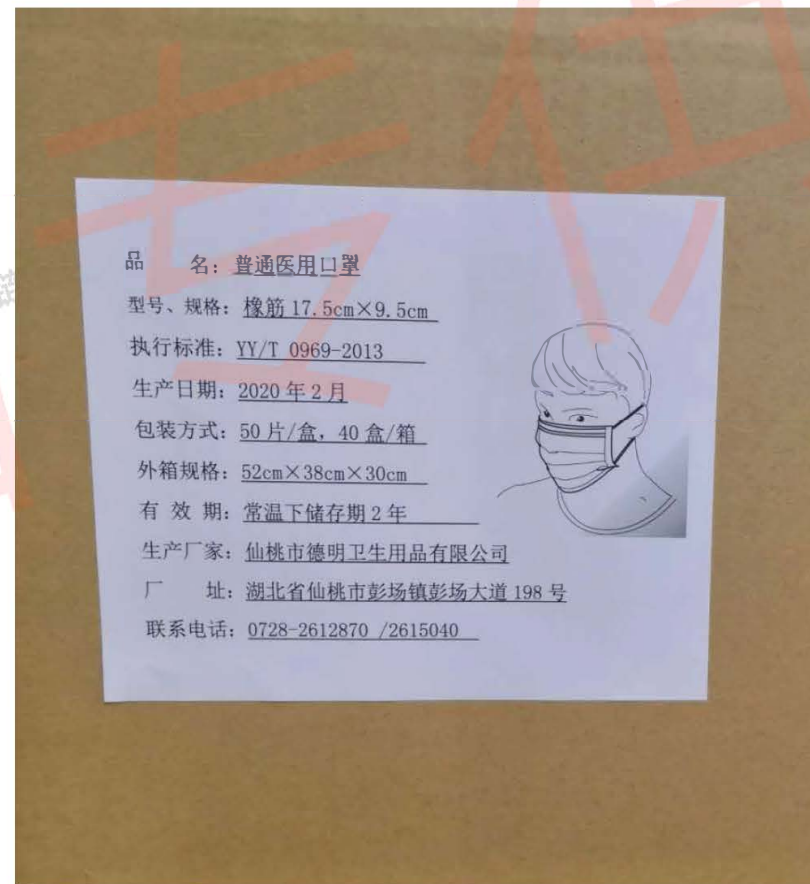
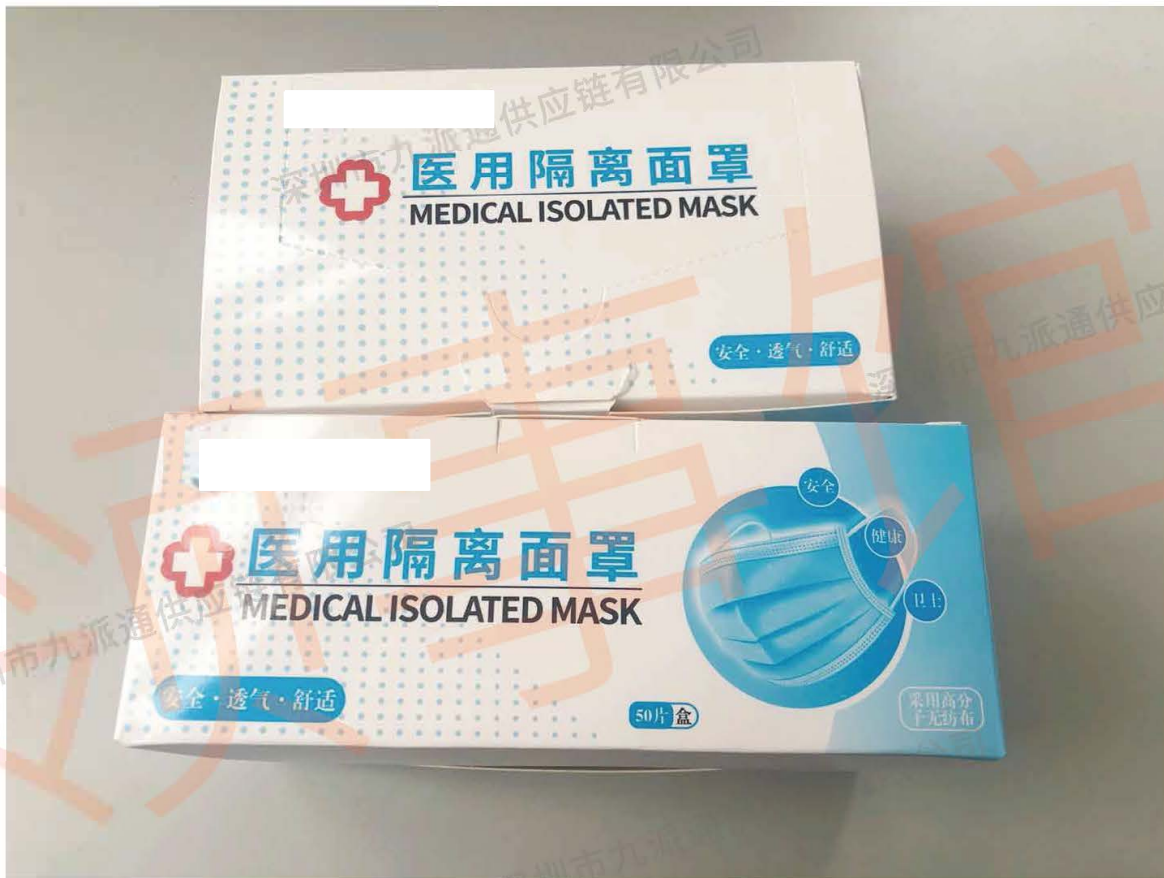
Product provided for consulates  
exclusively

Size: Rubber Band 17.5cm\*9.5cm

Packing: 50 pcs/box, 40 box/  
carton

Carton Size: 52cm\*38cm\*30cm

# Product Picture





# Product Qualification Certified by FDA



## Fiscal Year 2018 CERTIFICATION OF REGISTRATION

This certifies that:

**XIANTAO DEMING HEALTHCARE PRODUCTS CO., LTD.**  
No.198, Pengchang Ave. Pengchang Town, Xiantao City, Hubei  
Province, P.R.China, Xiantao, Hubei, 433018, CHINA

has completed the FDA Establishment Registration (as manufacturer, contract  
manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA: SUNGO TECHNICAL SERVICE INC.  
6050 W EASTWOOD AVE APT 201, CHICAGO,  
ILLINOIS 60630, USA  
Telephone: +1-855-957-7779 / E-mail: US.FDA@sungogroup.com

**Registration Number: 3008311433**  
**Device Listing#: See annex**

*SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.*



SUNGO CHINA OFFICE Tel: 021-58597193 Email:Shage2008@126.com Website: www.sungogroup.com  
Add: 13<sup>th</sup> Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China



## Fiscal Year 2018 CERTIFICATION OF REGISTRATION

Annex to Cert. No.: 2006US116538

Listing No	Code	Device Name
D201044	OEA	NON-SURGICAL ISOLATION GOWN (NON-SURGICAL ISOLATION GOWN)
D201046	KHA	MASK, SCAVENGING (MASK, SCAVENGING)
D201047	LYU	ACCESSORY, SURGICAL APPAREL (ACCESSORY, SURGICAL APPAREL)
D201048	FYF	CAP, SURGICAL (CAP, SURGICAL)
D246481	FXP	COVER, SHOE, OPERATING-ROOM (SHOE COVER)
D246482	KME	BEDDING, DISPOSABLE, MEDICAL (BEDDING, DISPOSABLE, MEDICAL)
D254359	FME	GOWN, EXAMINATION (PATIENT EXAM GOWN)

END OF THE ANNEX

SUNGO CHINA OFFICE Tel: 021-58597193 Email:Shage2008@126.com Website: www.sungogroup.com  
Add: 13<sup>th</sup> Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China

# Product Qualification

## Certified by CE

**nqa.**

### Compliance Report

**Applicant:** Xiantao Deming Healthcare Products Co., Ltd  
**Address:** 198#, Pengchang Ave, Pengchang town, Xiantao city, Hubei province, 433018, P. R. China

**Product:** Surgical Gown, Isolation Gown, Lab Coat, Coverall, Cap, Face Mask, Shoe Cover, Boot Cover, Bed Sheet, Pillow Case, Hairdressing Clothes, Beard Cover, Apron, Sleeve Cover, Spread Cover, Shopping Bag  
**Type:** See annex for details

**Product Classification:** Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02240  
Initial Issue Date: 09 Oct 2014

*Tony Chen*  
General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.

**nqa.**

### Annex to Report (No. 02240)

**Xiantao Deming Healthcare Products Co., Ltd**

Product Name	Type
Surgical Gown	115*127,115*137,120*140,130*150,
Isolation Gown	115*137,120*140,140*160,158*160
Lab Coat	110*120,110*125,115*130,120*135,120*140,125*140,130*145
Coverall	158*116,160*120,168*128,173*134,181*142,188*150,165*125,170*130,175*135,180*140,185*145
Cap	18*21",24".62*13.5cm,62*9cm
Face Mask	17.5*9cm
Shoe Cover	38*15cm,39*16cm,40*17cm
Boot Cover	40*40cm
Bed Sheet	240*140cm
Pillow Case	70*50cm
Hairdressing Clothes	100*140cm
Beard Cover	18",21"
Apron	110*70cm
Sleeve Cover	39*20cm
Spread Cover	210*180*20cm
Shopping Bag	According to the customer request

This annex is only valid if attached to the report mentioned above.

This report is the property of NQA and should be returned to NQA upon request.

# Production Qualification

  
**营 业 执 照**

统一社会信用代码 91429604X16153378G

名 称	仙桃市德明卫生用品有限公司
类 型	有限责任公司(自然人投资或控股)
住 所	仙桃市彭场镇彭场大道
法定代表人	廖明超
注 册 资 本	壹佰万圆整
成 立 日 期	2001年12月05日
营 业 期 限	2001年12月05日至2031年12月04日
经 营 范 围	无纺布制品、塑料制品、纸制品、服装的加工与销售；货物进出口、技术进出口；房屋出租。（法律、行政法规禁止的项目除外；法律、行政法规限制的项目取得许可后方可经营）。



登 记 机  2016 年 11 月 17 日

中华人民共和国国家工商行政管理总局监制



# Production Qualification

## 医疗器械生产许可证

许可证编号：鄂食药监械生产许：■

企业名称：仙桃市德明卫生用品有限公司

生产地址：湖北省仙桃市彭场镇彭场大道 198 号

法定代表人：廖明超

生产范围：

二类：6864 医用卫生材料及敷料。\*\*\*

企业负责人：廖明超

住 所：湖北省仙桃市彭场镇彭场大道 198 号

发证部门：湖北省食品药品监督管理局



# Production Qualification

## 中华人民共和国医疗器械注册证

注册证编号：鄂械注准 20152642120

注册人名称	仙桃市德明卫生用品有限公司
注册人住所	湖北省仙桃市彭场镇彭场大道 198 号
生产地址	湖北省仙桃市彭场镇彭场大道 198 号
代理人名称	(进口医疗器械适用)
代理人住所	(进口医疗器械适用)
产品名称	普通医用口罩
型号、规格	长方形口罩: 12cm × 7cm (S) 14.5cm × 9cm (M) 17.5cm × 9.5cm (L) 拱形口罩: 12cm × 11cm (S) 13cm × 12cm (M) 17cm × 13cm (L)
结构及组成	由非织造布、熔喷过滤布、鼻梁条、口罩带(或橡皮筋)组成。 由两层非织造布夹一层熔喷过滤布经折叠超声波复合而成。口罩上必须配有鼻夹,鼻夹由可弯折的可塑性材料制成。
适用范围	可用于普通环境下的一次性卫生护理,或者致病性微生物以外的颗粒如花粉等的阻隔或防护。(本口罩不能作为外科或防护口罩使用)
附件	产品技术要求,说明书
其他内容	
备注	

审批部门: 湖北省食品药品监督管理局

批准日期: 2015年06月08日  
有效期至: 2020年06月07日  
(有效期5年)

## 中华人民共和国医疗器械注册证

注册证编号: 鄂械注准 20152642121

注册人名称	仙桃市德明卫生用品有限公司
注册人住所	湖北省仙桃市彭场镇彭场大道 198 号
生产地址	湖北省仙桃市彭场镇彭场大道 198 号
代理人名称	(进口医疗器械适用)
代理人住所	(进口医疗器械适用)
产品名称	一次性使用手术衣
型号、规格	110cm × 130cm (S) 110cm × 142cm (M) 115cm × 135cm (L) 115cm × 140cm (XL) 120cm × 140cm (XXL)
结构及组成	一次性使用手术衣由前身、后身、袖子、系带等组成。
适用范围	本手术衣为标准性能手术衣,适用于进入手术室的医务人员进行一般性手术或进入无菌室的人员,穿在身上,可以有效地阻隔病人和医护人员之间感染源的传播。
附件	产品技术要求,说明书
其他内容	
备注	

审批部门: 湖北省食品药品监督管理局

批准日期: 2015年06月08日  
有效期至: 2020年06月07日  
(有效期5年)



# Business Qualification



## 营业执照

(副本)



统一社会信用代码

914403003496459874

名称 深圳市九派通供应链有限公司

类型 有限责任公司

法定代表人 李国梁

成立日期 2015年07月23日

住所 深圳市龙岗区坂田街道马安堂社区环城南路5号坂田国际中心D栋309

### 重要提示

1. 商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目，取得许可审批文件后方可开展相关经营活动。
2. 商事主体经营范围和许可审批项目等有关企业信用事项及年报信息和其他信用信息，请登录左下角的国家企业信用信息公示系统或扫描右上方的二维码查询。
3. 各类商事主体每年须于成立周年之日起两个月内，向商事登记机关提交上一自然年度的年度报告。企业应当按照《企业信息公示暂行条例》第十条的规定向社会公示企业信息。

登记机关



2019年05月10日

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

国家市场监督管理总局监制