ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

Fiscal Year 2020
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 Communications:
SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.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 global service FDA

SUNGO
Executive Director
Issued: Jan. 8 2020
Cert. No.: 2006US116558
Expiration Date: Dec. 31 2020
SUNGO global service CERTIFIED

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Cert. No.: 2006US116558

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

END OF THE ANNEX

XIANTAO DEMING HEALTHCARE PRODUCTS CO., LTD
198#, PENGCHANG AVE. PENGCHANG TOWN, XIANTAO CITY, HUBEI PROVINCE, 433018. P.R. CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Surgical mask
Style No.	:	2020YZW034
Sample Color	:	(A)white+blue
Manufacturer	:	Xiantao Deming Healthcare Products Co.,Ltd.
Proposed Care Instruction	:	-
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 03, 2020
Testing Period	:	Apr 03, 2020 - Apr 24, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

Test Result

Medical Face Masks-Requirements and Test Methods
(EN 14683:2019)

Clause 5.2.2 Bacterial filtration efficiency (BFE)[**@]

	1#	2#	3#	4#	5#
(BFE), %	99.5	>99.9	99.8	99.6	99.7

Remark: Performance Requirement: Type I>95%, Type II>98%, Type IIR >98%
**: The test was carried out by external laboratory assessed as competent
@: This test method is not in CNAS accredited scope

Clause 5.2.3 Breathability
(EN 14683 :2019 Annex C, Flow rate 8 l/min)

Sample A

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm^2)	52.0	54.1	50.7	51.3	52.2

Remark: Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface

1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Number of Pass: 32
Overall result: Acceptable

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR:≥16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

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Clause 5.2.5 Microbial Cleanliness
(EN 14683: 2019 Annex D**)**

	1#	2#	3#	4#	5#
CFU/g	19	23	20	22	22

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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湖北省医疗器械质量监督检验研究院

检 验 报 告 首 页

报告编号：2020YZW034　　共 3 页　第 1 页

样品名称	普通医用口罩			样品编号	2020YZW034
	送样（✓）	抽样（/）	现场试验（/）		
商　　标	/			型号规格	长方形 17.5×9.5cm
委托方	仙桃市德明卫生用品有限公司			检验类别	应急注册检验
委托方地址	湖北省仙桃市彭场镇彭场大道 198 号			产品编号/批号	2020011001
生产单位	仙桃市瑞锋卫生防护用品有限公司			抽样单编号	/
受检单位	仙桃市瑞锋卫生防护用品有限公司			生产日期	2020 年 01 月 10 日
抽样单位	/			样品数量	28 个
抽样地点	/			抽样基数	/
抽样日期	/			检验地点	本院试验室
收样日期	2020 年 02 月 21 日			检验日期	2020-02-21～2020-02-29
检验项目	4.5 细菌过滤效率、4.6 通气阻力、4.7.1 微生物指标				
检验依据	YY/T 0969-2013《一次性使用医用口罩》				
检验结论	被检样品所检项目符合 YY/T 0969-2013《一次性使用医用口罩》标准的要求。 （检验报告专用章或检验单位公章） 签发日期 2020 年 2 月 29 日				
备　注	1）报告中的“——”表示此项不适用，报告中“/”表示此项空白。 2）企业指定检测项目。				

批准：　　审核：　　检验：

职务：　　复核：

湖北省医疗器械质量监督检验研究院

检 验 报 告

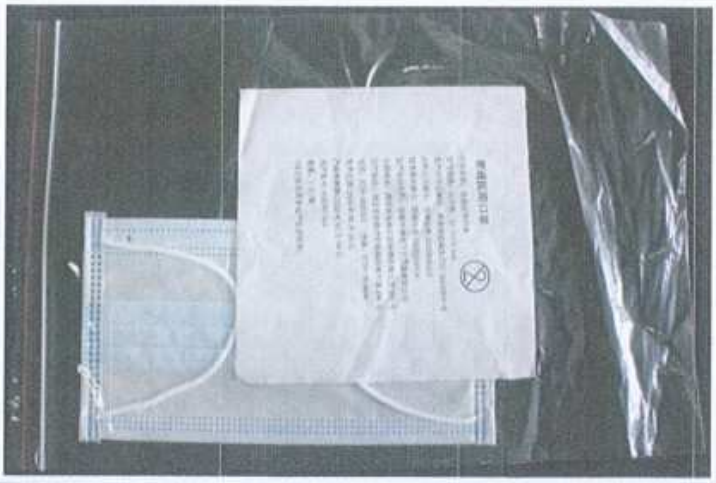
序号	检验项目	标准条款	标准要求		检验结果	单项结论	备注
1	细菌过滤效率（BFE）	4.5	口罩的细菌过滤效率应不小于 95%。		99%	符合	
2	通气阻力	4.6	口罩两侧面进行气体交换的通气阻力应不大于 49Pa/cm²。		（38－48）Pa/cm²	符合	
3	微生物指标	4.7.1	非灭菌口罩应符合表 1 的要求。	细菌菌落总数：≤100CFU/g；	＜1CFU/g	符合	
				大肠菌群：不得检出；	未检出		
				绿脓杆菌：不得检出；	未检出		
				金黄色葡萄球菌：不得检出；	未检出		
				溶血性链球菌：不得检出；	未检出		
				真菌：不得检出；	未检出		
	以下空白						

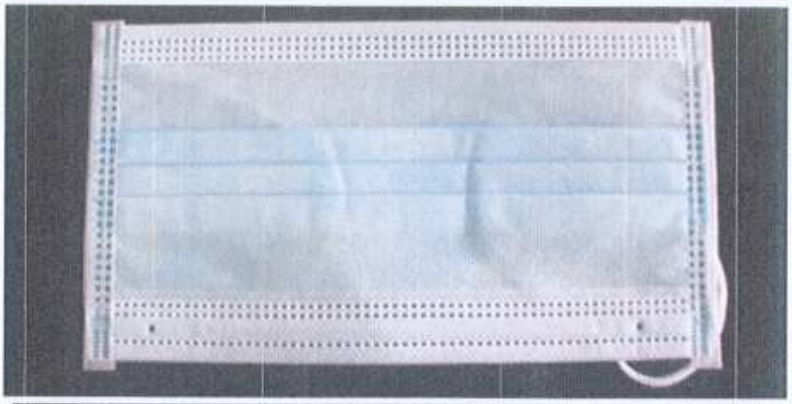
湖北省医疗器械质量监督检验研究院

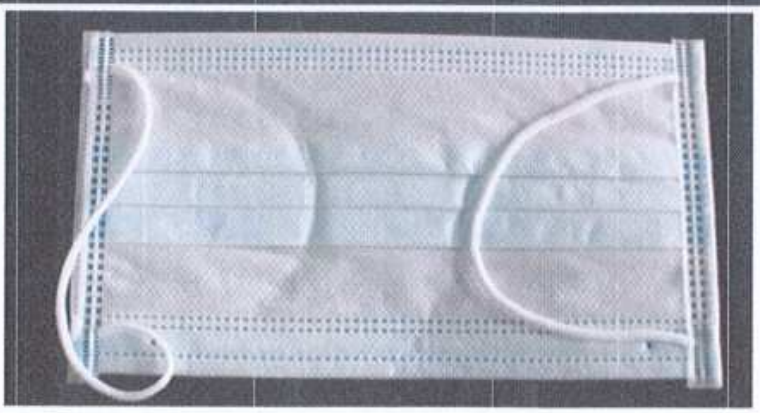
检 验 报 告 照 片 页

报告编号：2020YZW034

照片和说明







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）17.5m×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 04 日

有效期至：2020 年 06 月 03 日

（盖章）

第一类医疗器械备案信息表

备案号：鄂仙桃械备20200033号

备案人名称：	仙桃市德明卫生用品有限公司
备案人组织机构代码：	91429004X16153378G
备案人注册地址：	仙桃市彭场镇彭场大道198号
生产地址：	仙桃市彭场镇彭场大道198号
代理人：	/
代理人注册地址：	/
产品名称：	医用隔离面罩
型号/规格：	防护型 S号(12.5X8CM)、M号(14.5X9CM)、L号(17.5X9.5CM)
产品描述：	通常由高分子材料制成的防护罩、泡沫条和固定装置组成，非无菌提供，一次性使用。
预期用途：	用于医疗机构中检查治疗时起防护作用，阻隔体液、血液飞溅或泼溅。
备注：	
备案单位和日期：	仙桃市市场监督管理局 备案日期：2020年03月06日
变更情况：	

第一类医疗器械备案凭证

仙桃市德明卫生用品有限公司：

根据相关法规要求，对你单位第一类医疗器械：医用隔离面罩予以备案，备案号：鄂仙桃械备20200033号。

仙桃市市场监督管理局

（盖章）

日期：2020年03月06日

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)

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.