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U.S.A.:ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS

美国：ASTM F2100-19医疗口罩中使用的材料性能标准规范

EUROPE:EN 14683:2019 MEDICAL FACE MASKS-REQUIREMENTS AND TEST METHODS

欧洲：EN 14683：2019医疗口罩的要求和测试方法

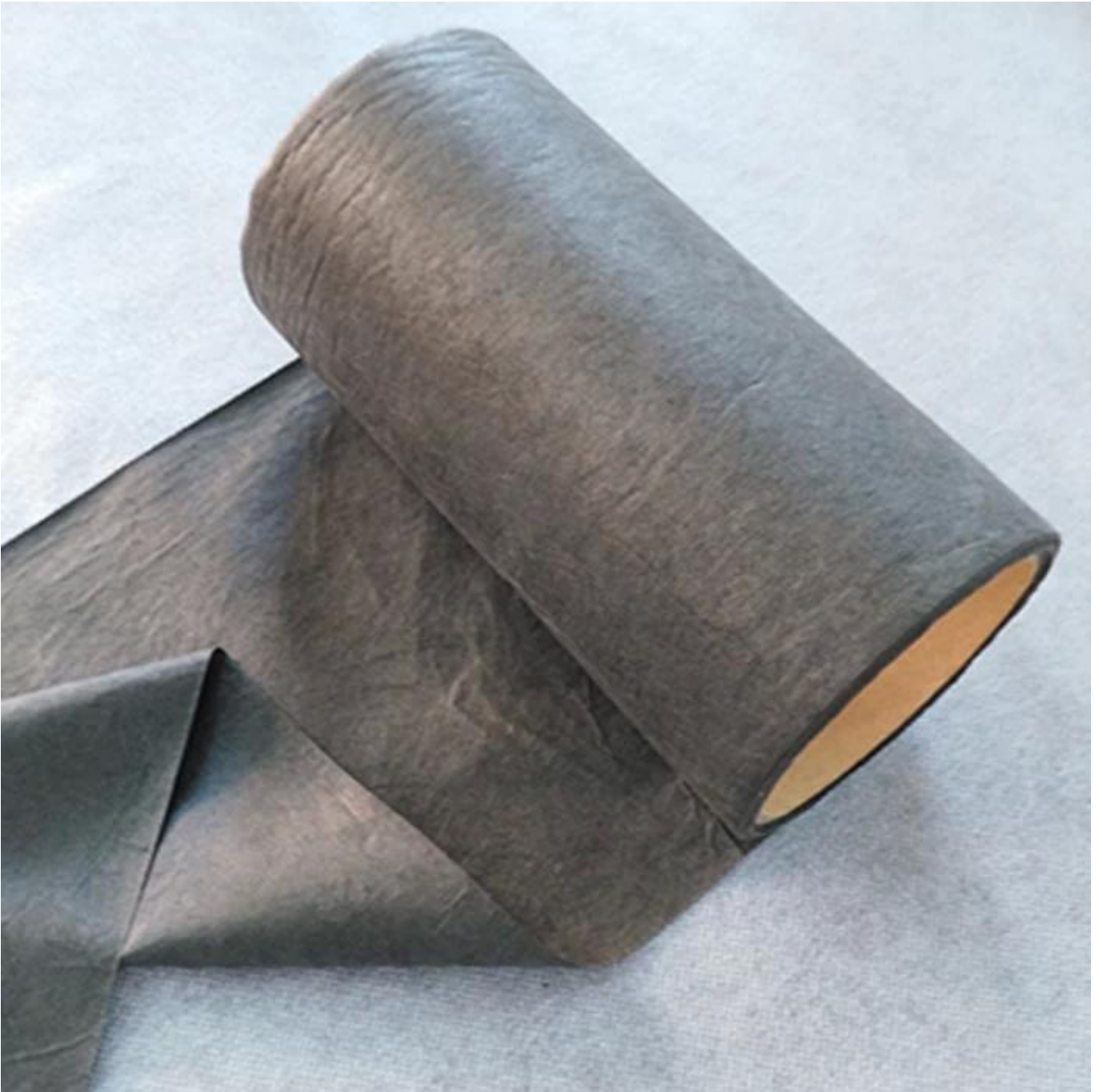
		ASTM F2100-19			EN 14683:2019 Barrier Levels		
		level 1	level 2	level 3	Type I	Type II	Type IIR
Barrier Testing	BFE% ASTM F2101, EN 14683	≥95	≥98		≥95	≥98	
	PFE% ASTM F2299	≥95	≥98		Not required		
	Synthetic Blood ASTM F1862, ISO22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Not required		Pass at ≥ 16.0 kPa(120 mmHg)
Physical Testing	Differential Pressure EN 14683	<5.0mmH ₂ O/cm ²	< 6.0 mmH ₂ O/cm ²		<40 Pa/cm ²		<60 Pa/cm ²
Safety Testing	Flammability 16 CFR Part 1610	Class 1(≥3.5 seconds)			See European Medical Directive (2007/47/EC, MDD 93/42/EEC)		
	Microbial Cleanliness ISO 11737-1	Not required			≤30 cfu/g		
	Biocompatibility ISO 10993	510 K Guidance recommends testing to ISO 10993			Complete an evaluation according to ISO 10993		

項目	項目	単位 g/m³	測定値 測定	規格値 規格	項目	単位 mm/分	項目	項目
P項目	FFP1	40	<40	> 80	測定値	95%	DOP	FFP1項目
	FFP2 / KF94	50	<160	> 94		95%	DOP	FFP2 / KF94項目
	FFP3	80	<190	> 97		95%	DOP	FFP3項目
KN項目	KN90	40	<80	> 90	測定値	85%	項目	KN90
	KN95 / N95	50	<100	> 95			項目	KN95項目N95
	KN100	80	<175	> 99.97			項目	KN99項目N100

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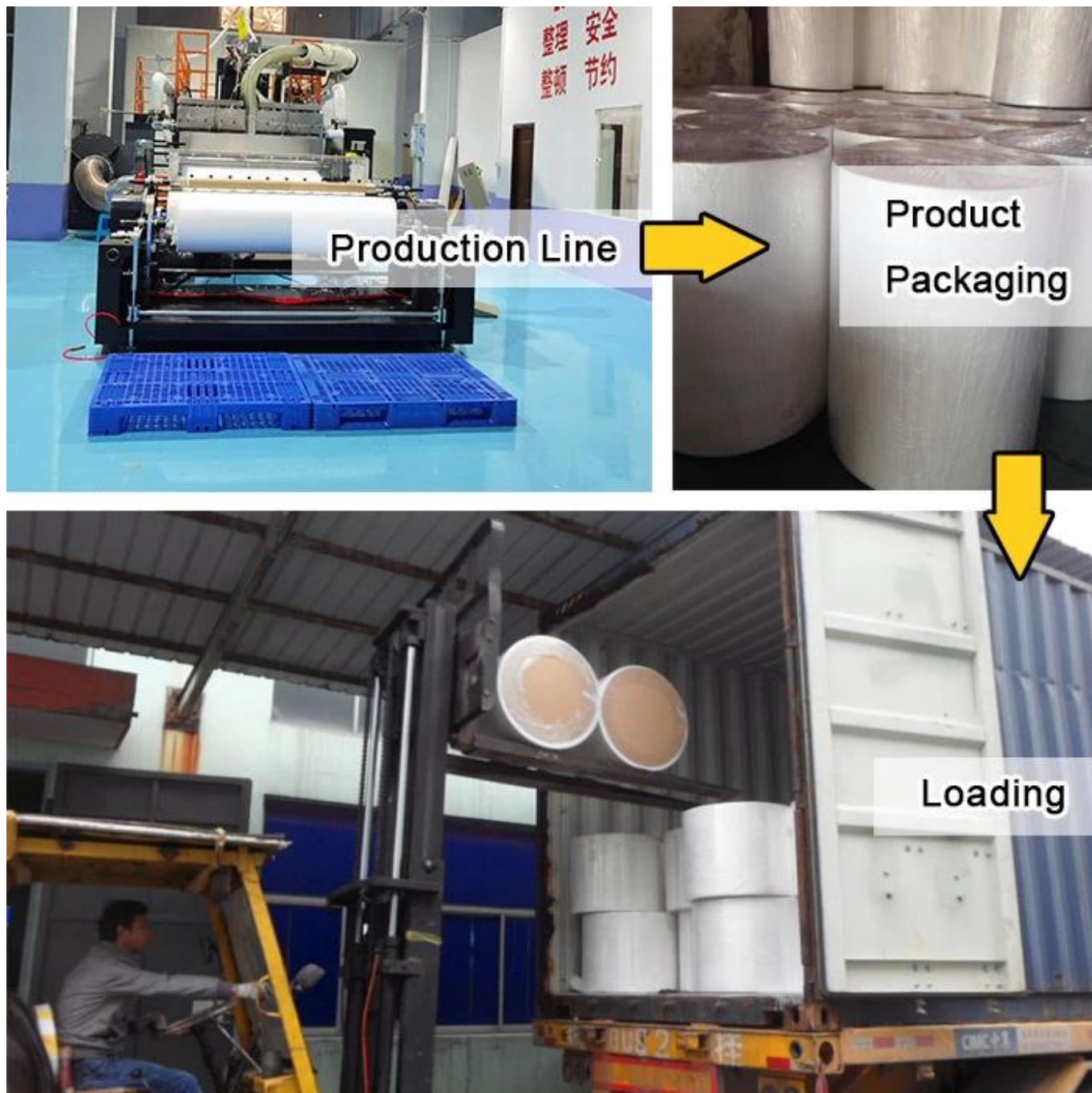
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中国认可
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实验室
TESTING
CNAS L1842



佛山中纺联检验技术服务有限公司
CNTAC Testing Service Co.,Ltd.(Foshan)

检测报告(Testing Report)

防伪查询网址(Security website): www.fcl-sz.org.cn
防伪码(Security code): 7815080747



报告编号(Report No): ZFLJ2642756

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Applicant Information (客户信息)

Applicant Name(委托单位) : FOSHAN GUIDE TEXTILE CO., LTD(佛山凯缙纺织品有限公司)
Applicant Address(委托单位地址) : Yonghao Industrial Park, Yongqing RD., Yanbu, Dali Town, Nanhai Dist.,
Foshan, G.D.528247, CHINA(佛山市南海区大沥镇盐步永青路永好产业园)

Sample Information (样品信息)

Sample Description(样品描述) : meltblown non woven fabric 25gsm(熔喷无纺布 25 克)
Style No.(款号) : SSKX-25
Specification(规格) : 260mm
Sample Quantity(样品数量) : 1roll (1 卷)
Colour(颜色) : white(白色)
Model(型号) : SSKX

- Sample Receiving date (收到样品的日期) : 2020-08-15
- Report date (报告日期) : 2020-08-21
- The original sample is stuck on the last paper. (送检样品原样粘贴在本报告的末页)

Test Performed (检验标准)

Judgement according to(评定依据):
ASTM F2100-2019e1 Standard Specification for Performance of Materials Used in Medical Face Masks Level 2
医用口罩用材料性能的技术规范 2 级
- Selected test(s) as requested by applicants. (本实验室根据客户要求完成以下检测内容)

Pronounce (声明)

The results shown in this report refer only to sample(s) tested unless otherwise stated. All the items are performed in the standard conditions, except the noted cases. (除非特别说明, 测试结果只对来样负责。所有测试项目均在标准规定的环境下进行, 有注明除外。)

Except for the requirement of the client, the test results and the conformity judgement of this report do not take the uncertainty of the test results into account. (除非客户要求, 本报告检测结果及符合性判定不考虑测量结果的不确定度。)

Signed for and on behalf of

CNTAC Testing Service Co.,Ltd.(Foshan)

Approved by
(批准)

张荣

(Except for microbiological project 微生物项目除外)

罗拉

(Microbiological project 微生物项目)



广东省佛山市南海区西樵镇南方技术创新中心一、三、四楼 1, 3&4/F., Nanfang Technology Innovation Center, Xiqiao, Nanhai District, Foshan, Guangdong, China
Tel: (86 757)86850633/86806656 Fax: 86850633 Http://www.fcl.org.cn

若对检测报告有异议, 应于收到报告之日起 15 日内向检测单位提出, 逾期不予受理。



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--- Test Result (测试结果) ---

Test Result(测试结果)	Requirements(评定条件)	Judgement(判定)
1. Sub-Micron Particulate Filtration Efficiency (PFE) at 0.1 micron (0.1 微米的颗粒过滤效率)		
<u>ASTM F2299/F2299M-03(R 2017)</u>		
Aerosol: PSL, Test area: 100cm ² , Airflow: 32L/min, Sampling time: 1min, Thickness: 2.3μm, Basis Weight: 25.0g/m ² (气溶胶类型: PSL, 测试面积: 100cm ² , 测试流量: 32L/min, 采样时间: 1min, 厚度: 2.3μm, 单位面积质量: 25.0g/m ²)		
Unit(单位): <%>		
sample 1#(样品 1)	98.8 ≥ 98	Pass(合格)
sample 2#(样品 2)	99.0	
sample 3#(样品 3)	98.6	
sample 4#(样品 4)	98.1	
sample 5#(样品 5)	98.1	
Minimum(最小值)	98.1	
2. Bacterial Filtration Efficiency(细菌过滤效率) <u>ASTM F 2101-19</u>		
Flow rate: 28.3L/min, Test area: 77cm ² , Test bacteria culture: Staphylococcus aureus ATCC 6538, Particle Diameter: 3.0μm, Inside of the test mask was facing towards the challenge aerosol, The average plate count results of the positive controls: 2.6×10 ³ CFU, The average plate count results of the negative controls: <1CFU(气溶胶流速: 28.3L/min, 测试面积: 77cm ² , 试验菌种: 金黄色葡萄球菌 ATCC 6538, 平均颗粒直径: 3.0μm, 口罩内侧面朝向气溶胶室, 阳性质控值: 2.6×10 ³ CFU, 阴性质控值: <1CFU)		
Unit(单位): <%>		
sample 1#(样品 1)	99.9 ≥ 98	Pass(合格)
sample 2#(样品 2)	99.9	
sample 3#(样品 3)	99.9	
sample 4#(样品 4)	99.9	
sample 5#(样品 5)	99.9	





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Original (送检样品原样)



===== End of Report (检测报告结束) =====



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