

EN 14683:2019 医疗口罩的要求和测试方法

材料	PP			
重量	25 GSM	40 GSM		
颜色	白色			
规格	EN14683:2019 / IIR / R / ASTM F2100:2019 / 1 / 2 / 3 / FFP1 / FFP2 / KN95 / KN99 / KF94 / N95 / N100			
长度	17.5 / 26 cm	25/26 cm		
过滤效率	BFE99%	BFE 99.5% / 100%		
流量	32L / min PFE NaCl 98%+	85L / min PFE NaCl 95%+	85L / min PFE NaCl 99%+	95L / min NaCl DEHS PFE 95%+
呼吸阻力	1000/2500 Pa	1300 Pa		
头围	43 / 73cm	55cm		
耳带	3/2 / 40 / 40	2 / 40 / 40		
重量	15-16kg / 14-15 kg / 32-35 kg	26-28kg / 27-29 kg		
尺寸	49.5x49.5x54.5 / 73 * 73 * 52.5 cm	49.5x49.5x54.5 cm		

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

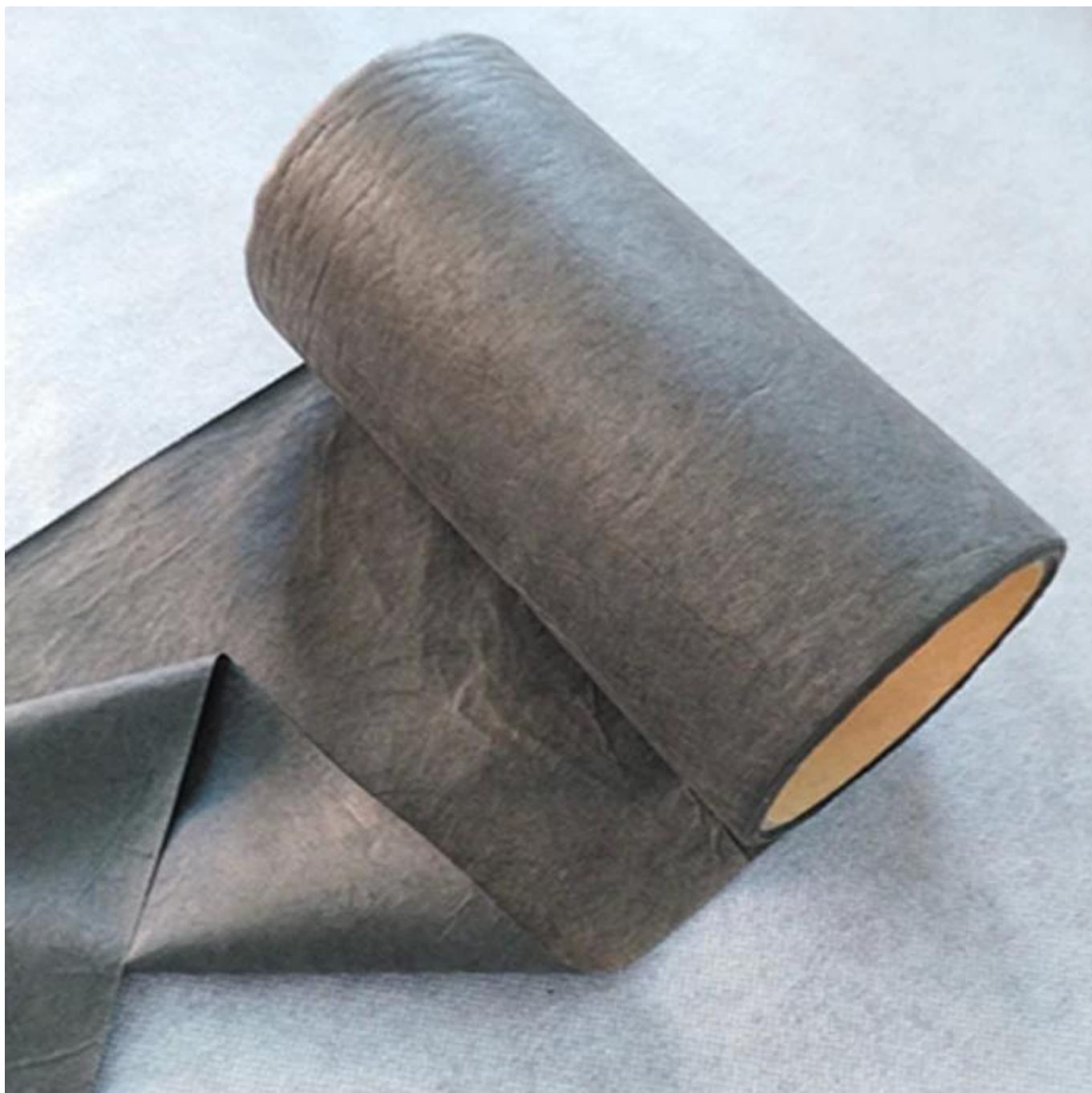
		ASTM F2100-19			EN 14683:2019 Barrier Levels		
		level 1	level 2	level 3	Type I	Type II	Type IIR
Barrier Testing	BFE% ASTM F2101, EN 14683	≥95	≥98		≥95	≥98	
	PFE% ASTM F2299	≥95	≥98		Not required		
	Synthetic Blood ASTM F1862, ISO22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Not required		Pass 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		

类型	规格	重量 g / m ³	流量 Pa	过滤效率 %	呼吸阻力 Pa	流量 L / min	材料	规格
P 型	FFP1	40	<40	> 80		95L	DOP	FFP1
	FFP2 / KF94	50	<160	> 94		95L	DOP	FFP2 / KF94
	FFP3	80	<190	> 97		95L	DOP	FFP3
KN 型	KN90	40	<80	> 90		85L	NaCl	KN90
	KN95 / N95	50	<100	> 95			NaCl	KN95 / N95
	KN100	80	<175	> 99.97			NaCl	KN99 / N100

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[PP](#)

PP



Production Line



Product Packaging



Loading



FOSHANGUIDE TEXTILE CO.,LTD
 2005
 1.6M 1.9M 2.1M 2.4M 2.5M 3.2M 3.7M 4.8M
 pp
 sms



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	Page 1 of 3	

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 stucked 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)

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

罗拉越 (Microbiological project 微生物项目)





中国认可
国际互认
检测
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)

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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(气体流速: 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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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。

問 題

問	答
Q1	A1
Q2 MOQ	A2 1
Q3	A3
Q4	A4 PC
Q5	A5
Q6	A6 24
Q7	A7 OEM
Q8	A8 24