

MEDICAL FACE MASK TESTS AND REQUIREMENTS

U.S.A.: ASTM F2100-21 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS
 EUROPE: EN 14683:2019 MEDICAL FACE MASKS – REQUIREMENTS AND TEST METHODS

		ASTM F2100-21			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	<5.0 mmH 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	Long-term exposure and common methods are in vitro cytotoxicity (MEM elution), irritation, skin sensitization			Complete an evaluation according to ISO 10993		
Sampling ANSI/ASQC Z1.4 ISO 2859-1		<ul style="list-style-type: none"> AQL 4% for BFE, PFE, Delta P, Synthetic Blood, Flammability Note: recommend 96 samples for each test. 32 samples per lot, 3 nonconsecutive lots			<ul style="list-style-type: none"> Minimum of 5 masks up to an AQL of 4% for BFE, Delta P and Microbial Cleanliness 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing) 		

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