TTRI
財團法人紡織產業綜合研究所
Taiwan Textile Research Institute

EN 14683:2019 Medical face masks. Requirements and test methods

Currency: US $

Test Items	Test Standards	Prices (Standard)	Sample required	Working Days	
				Regular	Express
Bacterial Filtration Efficiency (5pcs)	EN 14683 Annex B	$ 370	7	Inquiry	Pause
Differential pressure (5pcs)	EN 14683 Annex C	$ 100	7		
Splash resistance pressure (32pcs)	ISO 22609	$ 290	35		
Microbial cleanliness (Bioburden) (5pcs)	EN 14683 / EN ISO 11737-1	$ 340	7		
		$ 1,100			

Table 1 — Performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

ASTM F2100 - 19 Standard Specification for Performance of Materials Used in Medical Face Masks

Currency: US $

Test Items	Test Standards	Prices (Standard)	Sample required	Working Days	
				Regular	Express
Bacterial Filtration Efficiency (5pcs)	ASTM F2100 9.1 / ASTM F2101	$ 370	7	Pause	Pause
Differential pressure (5pcs)	ASTM F2100 9.2 / EN 14683 Annex C	$ 100	7		
Particulate Filtration Efficiency (5pcs)	ASTM F2100 9.3 / ASTM F2299	$ 300	7		
*Resistance to Penetration by Synthetic Blood (32pcs) Please indicate the level of resistance in the	ASTM F2100 9.4 / ASTM F1862	$ 290	35		
Flammability (10pcs)	ASTM F2100 9.5 / 16 CFR PART 1610	$ 35	12		
A single sampling plan providing an AQL of 4.0 % would require 32 specimens.		$ 1,595			

Five samples may be sufficient for periodic R&D or verification testing but is not recommended for FDA submission.
Five samples for Bacterial Filtration Efficiency (BFE), Differential Pressure (Delta P), and Particle Filtration Efficiency (PFE) may no longer be adequate for FDA submissions.

TABLE 1 Medical Face Mask Material Requirements by Performance Level

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial filtration efficiency, %	≥95	≥98	≥98
Differential pressure, mm H_2O/cm^2	<5.0	<6.0	<6.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥95	≥98	≥98
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	80	120	160
Flame spread	Class 1	Class 1	Class 1

Bank Name: Mega International Commercial Bank Co., Ltd, Tu-Cheng Branch
Bank Address: 276, Chung-Yang Road, Sec. 2, Tu-Cheng Dist., New Taipei City, Taiwan, R.O.C.
A/C No: 05653015386
A/C Name: Taiwan Textile Research Institute
Swift Code: ICBCTWTP056

PS: The banking charges of the wire transfer are borne by the client.
The international postage of report is US $20.
The above offer is valid for one week.
The clients shall pay the testing fee within 3 days of receiving the samples and e-mail the receipt to TTRI.
Please indicate the "testing fee" in the receipt of the remittance