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# ASTM

#### 英文全稱為 American Society for Testing and Materials

根據ASTM Standard F2100,口罩依過濾能力 (BFE和PFE)、壓力差 (Delta P)、液體阻擋能力 (Fluid Resistance)及阻燃能力 (Flammability),可分成三個防護級別,當中以Level 1 為最低、Level 3為最高級別,而Level 2和Level 3的口罩都能阻擋98%或以上的微粒 (0.1 µm),有效阻擋細菌病毒透過飛沫傳播。

#### **ASTM** (American Society for Testing and Materials)

According to ASTM Standard F2100, surgical face mask material performance is based on testing for bacterial filtration efficiency, particle filtration efficiency, differential pressure, resistance to penetration by synthetic blood, and flammability. Level 1 masks have the lowest barrier of protection, while Level 3 masks have the highest barrier of protection. Both Level 2 and Level 3 masks can filter ≥ 98% of 0.1 micron particles, which can effectively block the spread of bacteria and viruses through droplets.



## 產品認證

## **Product Qualifications**

## Level 3 一次性三層外科口罩 3-ply Surgical Mask

MedFort® 30 (Level 3) **30片獨立防潮包裝** 

30pcs moisture-proof individual pack

MedFort<sup>®</sup> 50 (Level 3) **50片非獨立包裝 50pcs non-individual pack** 

美國 ASTM Level 3 最高認證

**US ASTM Level 3 Highest Standard** 

BFE 細菌過濾 ● PFE 微粒過滤 ● VFE 病毒過滤 particle filtration ● VFE viral filtration

≥99%

## Level 2 一次性三層外科口罩 3-ply Surgical Mask

MedFort<sup>®</sup> 30 (Level 2)
30片獨立防潮包裝
30pcs moisture-proof individual pack

MedFort<sup>®</sup> 50 (Level 2) **50片非獨立包裝 50pcs non-individual pack** 

美國 ASTM Level 2 認證

**US ASTM Level 2 Standard** 

>98%

- 歐盟 EN 14683 Type IIR 最高防護級別 EN14683 Type IIR Highest European Standard
- Delta P 4.1\* 高透氣度優質濾層 \*壓力差 mm H₂O/cm²
  Delta P 4.1\* Quality filter layer with super breathability \*mm H₂O/cm²
- GB 15979 2002 衛生標準 GB 15979 - 2002 Hygienic Standard
- ISO 14644 1 Class 7 無塵車間標準 ISO 14644 - 1 Class 7 Cleanroom Standard
- ISO 10993 5 細胞毒性測試 ISO 10993 - 5 Cytotoxicity Test
- ISO 10993 10 刺激性與皮膚過敏測試 ISO 10993 10 Irritation and skin sensitization Tests
- 三層保護過濾設計, 有效過濾細菌及微粒子:
  - 外層抗水物料
  - 中層優質熔噴布夾心過濾
  - 內層防敏柔順肌膚親和物料
- 簡易舒適掛耳設計
- 醫生及醫護人員適用
- 儲存方法:存放於陰涼乾燥地方, 避免陽光直接照射
- 保存期限:三年

- Three-layer protection filter design, effectively filter bacteria and particles :
  - Outer layer : water-resistant material
  - Middle layer : high quality meltblown cloth sandwich filter
  - Inner layer : anti-allergic and skin-friendly supple material
- Elastic and comfortable ear loops
- Applicable for medical use
- Storage : Store in a cool,dry place away from direct sunlight
- Storage period : 3 years







新冠肺炎肆虐,疫情初期,站在前線的醫護界,物資緊絀,更遑論廣大香港市民。

MedFort®醫堡®的創辦人有見及此,決心出一分力為香港人製作高品質的醫療級別口罩,希望減少日常感染機會,間接支援醫護界別,舒緩物資短缺的壓力。

「香港製造」,曾經是香港人的驕傲。就讓我們秉承這一份自強不息的信念,盡一分力, 守護我們的香港。

The Coronavirus Disease (COVID-19) has been raging. In the early days of the epidemic, medical masks were in short supply for medical profession standing on the front lines, let alone the general public.

In view of this, the founder of MedFort® is determined to make a contribution to the production of high-quality medical-grade masks for Hong Kong people, hoping to reduce the chance of daily infections, indirectly support the medical profession, and alleviate the pressure of shortage of medical resources.

"Made in Hong Kong" was once the pride of Hong Kong. Let us uphold this belief of self-improvement and do our best to protect our home - Hong Kong.















































醫堡®在港自設工場生產口罩,廠房位於新界佔地約 5,300 平方呎、已獲取 Level 7 優質標準的無塵工作間內。廠內現有5條成人裝口罩生產線及1條中童裝口罩生產線,透過全自動化的設備,每月共生產約500萬個高品質口罩,加上員工日以繼夜輪班工作,確保口罩供應穩定。 MedFort® has its own mask factory in Hong Kong. Located in an area of approximately 5,300 square feet in the New Territories, MedFort® produces masks in a dust-free cleanroom that has successfully obtained ISO Class 7 quality standards. There are 5 production lines for adult masks and 1 production line for junior masks in the factory. With the use of fully automated equipment, we can produce a total of 5 million high-quality masks every month.



■ 為確保原材料熔噴布的品質,醫堡®更直接在廣東新會注資興建屬於自己的熔噴布製造工場,以確保每一片由我們出產之口罩,都呈現優質、可信賴的品質。

To ensure the quality of the raw material meltblown cloth, MedFort® built its own meltblown cloth manufacturing plant in Xinhui, Guangdong Province. Each mask produced by us is a showcase of quality and reliability.







# 測試及認證總覽

**Test & Certification Summary** 





ASTM 認證	ASTM Certification
	ASTM CELLICATION

	測試標準 Testing Standard	測試項目	測試機構	MedFort® 口罩表現	LEVEL 2		LEVEL 3	
		***************************************		MedFort® Performance	要求 Standard	通過 Pass	要求 Standard	通過 Pass
	ASTM F2100-19 美國材料和試驗協會 口罩防護強度測試標準	細菌過濾率 BFE @3 μm (微米)	美國 Nelson Labs US Nelson Labs	99.90%	≥98%	<b>/</b>	≥98%	<b>/</b>
		顆粒過濾率 PFE @0.1 μm (微米)	美國 Nelson Labs US Nelson Labs	99.96% - 99.99%	≥98%	<b>✓</b>	≥98%	<b>/</b>
		液體阻力 Fluid Resistance to synthetic blood (mmHg)	美國 Nelson Labs US Nelson Labs	通過 Pass	120	<b>✓</b>	160	<b>/</b>
ASTM F2100-19 Mask Test Standard	壓力差 Delta P (mm H <sub>2</sub> O/cm²)	美國 Nelson Labs US Nelson Labs	3.6 - 4.1	<6.0	<b>\</b>	<6.0	<b>/</b>	
	阻燃程度 Flammability	美國 Nelson Labs US Nelson Labs	通過 Pass	Class 1	<b>\</b>	Class 1	<b>/</b>	

### 歐盟 EN14683 認證 EN14683 European Standard

測試標準	測試項目	測試機構	MedFort®口罩表現	Type IIR	
Testing Standard	Testing Item	Testing Agency	MedFort® Performance		通過 Pass
	細菌過濾率 BFE @3 μm (微米)	美國 Nelson Labs US Nelson Labs	99.90%	≥98%	<b>/</b>
EN14683: 2019 歐盟口罩防護強度 測試標準	液體阻力 Fluid Resistance to synthetic blood (kPa)	美國 Nelson Labs US Nelson Labs	通過 Pass	≥16	<b>✓</b>
EN14683: 2019 Mask Test Standard	壓力差 <mark>Delta P</mark> (Pa/cm²)	美國 Nelson Labs US Nelson Labs	40.3	<60	<b>✓</b>
	微生物清潔度 Microbial Cleanliness (cfu/g)	美國 Nelson Labs US Nelson Labs	通過 Pass	≥30	<b>/</b>

## ISO 認證 ISO Certifications

ISO 10993-5	細胞毒性測試 Cytotoxicity	EPINTEK	通過 Pass
ISO 10993-10	刺激性測試 Irritation 皮膚敏感性測試 Skin Sensitization	EPINTEK	通過 Pass
ISO 14644-1_2015	無塵空間認證 Cleanroom	The Lab (Asia) Ltd	第七級 Class 7

## 額外認證 Other Certifications

	香港Q嘜優質產品計劃 Hong Kong Q-Mark Product Scheme	Q嘜認證 Q-Mark Certification	香港優質標誌局 Hong Kong Q-Mark Council	獲取 Awarded
·····································			通過 Pass	

## 額外標準 Additional Qualifications

ASTM F2101 口罩防護強度測試標準 ASTM F2101 Mask Test Standard	病毒過濾效率 VFE @3.0 ± 0.3 μm(微米)	美國 Nelson Labs US Nelson Labs	99.90%
GB15979-2002	口罩衛生 Hygienic Standard	STC (The Hong Kong Standards and Testing Centre)	通過 Pass

