MedFort® 醫堡
Healthcare Limited

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地址：香港新界粉嶺安全街10-12號堅達中心
Address : Smile Centre, 10-12 On Chuen Street, Fanling,
New Territories, Hong Kong

查詢電郵 Email :
enquiry@medfort.com.hk

銷售熱線 Enquiry :
(852) 3955 8592

服務時間 Opening Hours :
星期一至五 Mon - Fri : 0900－1300 / 1400－1800
星期六 Sat : 0900－1300
星期日及公眾假期休息 Closed on Sundays and Public Holidays

Instagram
Facebook
medfort.com.hk

ASTM Level 3

英文全稱為 **A**merican **S**ociety for **T**esting and **M**aterials

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 **S**ociety for **T**esting and **M**aterials)

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.

for JUNIOR

MedFort® 醫堡 Healthcare Limited

產品認證
Product Qualifications

Level 3 一次性三層外科口罩 3-ply Surgical Mask

- 成人裝 For Adult
- 中童裝 For Junior

MedFort® 30 (Level 3) **30片獨立防潮包裝** **30pcs moisture-proof individual pack**	MedFort® 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 bacterial filtration • **PFE** 微粒過濾 particle filtration • **VFE** 病毒過濾 viral filtration **≥99%**	

- **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 H_2O/cm^2**
  Delta P 4.1* Quality filter layer with super breathability *mm H_2O/cm^2
- **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

Q嘜優質產品
Q-Mark Product
Licence No : C843

CE

香港製造
MADE IN HONG KONG

政府認可醫療檢測機構
HKMPDC NSTA SPECIALIST
指定口罩供應商

MedFort® 醫堡
Healthcare Limited

產品規格
Product Specifications

成人裝 For Adult

30片獨立防潮包裝
30 pcs moisture-proof individual pack

50片非獨立包裝
50 pcs non-individual pack

30片獨立防潮包裝 30 pcs moisture-proof individual pack	
產品編號 Item No	ADL3W30
口罩顏色 Mask Colour	白色 White
口罩尺寸 Mask Size	17.5 cm x 9.5 cm
耳帶長度 Ear Loop Size	170 mm
口罩盒尺寸 Box Size	213 mm x 115 mm x 100 mm (闊Width) (高Height) (長Length)
紙箱尺寸 (50盒口罩) Carton Size (50 boxes)	515 mm x 620 mm x 455 mm (闊Width) (高Height) (長Length)
口罩盒重量 Box Weight	0.2 kg / 盒 box 11.39 kg / 箱 carton (50 盒 boxes)

50片非獨立包裝 50 pcs non-individual pack	
產品編號 Item No	ADL3W50
口罩顏色 Mask Colour	白色 White
口罩尺寸 Mask Size	17.5 cm x 9.5 cm
耳帶長度 Ear Loop Size	170 mm
口罩盒尺寸 Box Size	193 mm x 105 mm x 100 mm (闊Width) (高Height) (長Length)
紙箱尺寸 (50盒口罩) Carton Size (50 boxes)	535 mm x 565 mm x 415 mm (闊Width) (高Height) (長Length)
口罩盒重量 Box Weight	0.19 kg / 盒 box 10.48 kg / 箱 carton (50 盒 boxes)

中童裝 For Junior

30片獨立防潮包裝
30 pcs moisture-proof individual pack

50片非獨立包裝
50 pcs non-individual pack

30片獨立防潮包裝 30 pcs moisture-proof individual pack	
產品編號 Item No	JRL3W30
口罩顏色 Mask Colour	白色 White
口罩尺寸 Mask Size	14.5 cm x 9.5 cm
耳帶長度 Ear Loop Size	165 mm
口罩盒尺寸 Box Size	183 mm x 115 mm x 100 mm (闊Width) (高Height) (長Length)
紙箱尺寸 (50盒口罩) Carton Size (50 boxes)	520 mm x 595 mm x 385 mm (闊Width) (高Height) (長Length)
口罩盒重量 Box Weight	0.17 kg / 盒 box 9.95 kg / 箱 carton (50 盒 boxes)

50片非獨立包裝 50 pcs non-individual pack	
產品編號 Item No	JRL3W50
口罩顏色 Mask Colour	白色 White
口罩尺寸 Mask Size	14.5 cm x 9.5 cm
耳帶長度 Ear Loop Size	165 mm
口罩盒尺寸 Box Size	163 mm x 105 mm x 100 mm (闊Width) (高Height) (長Length)
紙箱尺寸 (50盒口罩) Carton Size (50 boxes)	520 mm x 555 mm x 345 mm (闊Width) (高Height) (長Length)
口罩盒重量 Box Weight	0.17 kg / 盒 box 9.7 kg / 箱 carton (50 盒 boxes)

MedFort® 醫堡
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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.

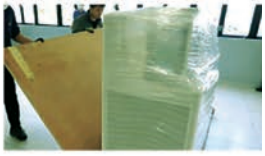
"Made in Hong Kong" was once the pride of Hong Kong. Let us uphold this belief of self-improvement and do our best to protect our home - Hong Kong.

















MedFort® 醫堡
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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 8 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 8 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.

MedFort® 醫堡
Healthcare Limited

測試及認證總覽
Test & Certification Summary

Nelson Labs
A Sotera Health company

STC

ASTM 認證 ASTM Certification

測試標準 Testing Standard	測試項目 Testing Item	測試機構 Testing Agency	MedFort® 口罩表現 MedFort® Performance	LEVEL 3 要求 Standard	LEVEL 3 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%	✓
	顆粒過濾率 PFE @0.1 μm (微米)	美國 Nelson Labs US Nelson Labs	99.96% - 99.99%	≥98%	✓
	液體阻力 Fluid Resistance to synthetic blood (mmHg)	美國 Nelson Labs US Nelson Labs	通過 Pass	160	✓
ASTM F2100-19 Mask Test Standard	壓力差 Delta P (mm H_2O/cm^2)	美國 Nelson Labs US Nelson Labs	3.6 - 4.1	<6.0	✓
	阻燃程度 Flammability	美國 Nelson Labs US Nelson Labs	通過 Pass	Class 1	✓

歐盟 EN14683 認證 EN14683 European Standard

測試標準 Testing Standard	測試項目 Testing Item	測試機構 Testing Agency	MedFort® 口罩表現 MedFort® Performance	Type IIR 要求 Standard	Type IIR 通過 Pass
EN14683: 2019 歐盟口罩防護強度 測試標準	細菌過濾率 BFE @3 μm (微米)	美國 Nelson Labs US Nelson Labs	99.90%	≥98%	✓
	液體阻力 Fluid Resistance to synthetic blood (kPa)	美國 Nelson Labs US Nelson Labs	通過 Pass	≥16	✓
EN14683: 2019 Mask Test Standard	壓力差 Delta P (Pa/cm^2)	美國 Nelson Labs US Nelson Labs	40.3	<60	✓
	微生物清潔度 Microbial Cleanliness (cfu/g)	美國 Nelson Labs US Nelson Labs	通過 Pass	≤30	✓

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
歐盟CE認證 EU CE Marking			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

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Sponsor:
MedFort Healthcare Limited
Smile Centre,
10-12 On Chuen Street,
Fanling, New Territories,
HONG KONG

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	MF-001
Study Number:	1316472-S01
Study Received Date:	02 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~174 mm x ~170 mm
Positive Control Average:	1.7 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

McKenna Wild electronically approved for
Study Director James Luskin

30 Jul 2020 15:15 (+00:00)
Study Completion Date and Time

MedFort® Healthcare Limited 醫堡

Results:

Test Article Number	Percent BFE (%)
1	>99.9[a]
2	>99.9[a]
3	>99.9[a]
4	>99.9[a]
5	>99.9[a]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.0	39.6
2	4.1	40.3
3	3.9	38.3
4	4.0	38.8
5	3.6	35.7

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Nelson Labs
A Sotera Health company

Sponsor:
MedFort Healthcare Limited Smile Centre,
10-12 On Chuen Street,
Fanling, New Territories,
HONG KONG

Latex Particle Challenge Final Report

Test Article:	MF-001
Study Number:	1316471-S01
Study Received Date:	02 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 08
Deviation(s):	None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 30% relative humidity (RH) at 1722; 21°C, 29% RH at 1820
Average Filtration Efficiency:	>99.978%
Standard Deviation:	0.0165

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

McKenna Wild electronically approved for — 22 Jul 2020 14:53 (+00:00)
Study Director Curtis Gerow — Study Completion Date and Time

Nelson Labs
A Sotera Health company

Study Number 1316471-S01
Latex Particle Challenge Final Report

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	6	13,789	99.956
2	4	13,509	99.970
3	<1[a]	12,841	>99.9974
4	1	12,208	99.9918
5	3	12,189	99.975

[a] There were no detected particles penetrating this filter during testing.

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A Sotera Health company

Sponsor:
MedFort Healthcare Limited Smile Centre
10-12 On Chuen Street, Fanling
New Territories
HONG KONG

Synthetic Blood Penetration Resistance Final Report

Test Article:	MF-001
Study Number:	1325985-S01
Study Received Date:	29 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.7°C and 21% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Trang Truong electronically approved for
Study Director James Luskin

20 Aug 2020 00:10 (+00:00)
Study Completion Date and Time

MedFort® 醫堡 Healthcare Limited

Nelson Labs
A Sotera Health company

Sponsor:
MedFort Healthcare Limited Smile Centre
10-12 On Chuen Street, Fanling
New Territories, Hong Kong,
CHINA

Flammability of Clothing Textiles Final Report

Test Article:	MF-001
Study Number:	1316475-S01
Study Received Date:	02 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0073 Rev 06
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Article Side Tested:	Outside Surface
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Adam Brigham electronically approved for	20 Jul 2020 15:15 (+00:00)
Study Director Curtis Gerow	Study Completion Date and Time

Results:

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

IBE = Test Article ignited, but extinguished

Nelson Labs.
A Sotera Health company

Sponsor:
MedFort Healthcare Limited Smile Centre
10-12 On Chuen Street, Fanling
New Territories, Hong Kong,
CHINA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	MF-001
Study Number:	1325986-S01
Study Received Date:	29 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 202002096 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.0	30	<3	<32.9	<11.0
2	3.0	21	3	23.8	7.9
3	3.0	38	3	41.3	13.8
4	3.0	20	<3	<23.8	<7.6
5	2.9	44	<3	<46.5	<16.0
Recovery Efficiency	59.6%				

< = No Organisms Detected
Note: The results are reported as colony forming units (CFU) per mask.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Robert Putnam electronically approved — 19 Aug 2020 23:08 (+00:00)
Study Director Robert Putnam — Study Completion Date and Time

MedFort® 醫堡 Healthcare Limited

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	88%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Tryptic Soy Agar Potato Dextrose Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3-7 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 5-7 days at 20-25°C, then enumerated.

中国认可
国际互认
检测
TESTING
CNAS L10463

FINAL REPORT

Study Name: MedFort Face Mask- In Vitro Cytotoxicity Test

Study Number: MED202007707-01-EN

Sponsor

Name: MEDFORT HEALTHCARE LIMITED

Address: SMILE CENTRE, 10-12 ON CHUEN STREET, FANLING, NEW TERRITORIES, HONG KONG

Testing Facility

Name: EPIN Suzhou Ltd.

Address: No.558 Fenhu Avenue. Lili Town, Wujiang District, Suzhou, China

SUMMARY

1. Purpose

The purpose of this test is to determine the biological reactivity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article MedFort Face Mask extract.

2. Process Description

The suspended cells were dispensed in 96-well plate, and incubated in cell incubator (5% CO_2, 37°C) on the first day.

On the second day, the test article extract (100%, 75%, 50% and 25% in growth medium) was added to L-929 cells in 96-well plates and then incubated at 37°C in 5% CO_2 for another 24 h.

After 24 h incubation, observed the cell morphology first and 50 µL aliquot of MTT (1 mg/mL) was added. 2 h incubation later, the OD value was determinated.

3. Result

The MTT method results showed that the cytotoxicity ratio of the 100% test article extract was 78.5%. The results of control groups showed the test was valid.

4. Conclusion

Under the conditions of this study, the test article extract did not show potential toxicity to L-929 cells.

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FINAL REPORT

Study Name: MedFort Face Mask- Skin Irritation Test

Study Number: MED202007707-10-EN

Sponsor

Name: MEDFORT HEALTHCARE LIMITED

Address: SMILE CENTRE, 10-12 ON CHUEN STREET, FANLING, NEW TERRITORIES, HONG KONG

Testing Facility

Name: EPIN Suzhou Ltd.

Address: No.558 Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

SUMMARY

1. Purpose

To evaluate the potential skin irritation caused by the extraction of the test article extract contacting with the skin surface of rabbits.

2. Process Description

Test article was whole sampling by 3 cm^2: 1 mL, extraction condition was 37°C, 72 h. Extraction solvents were 0.9% sodium chloride (SC) and sesame oil (SO).

The rabbits used to conduct experiments were healthy and with intact skin. The fur on the back of the rabbit was clipped within 24 h before the test started, a sufficient area on both sides of the spine for application and observation of all test sites (approximately 10 cm×15 cm). The 2.5 cm×2.5 cm absorbent gauze patches were soaked with 0.5 mL extraction of test article or control and put the patches on the skin on each side of each rabbit directly, then wrapped the test sites with bandage (occlusive) for at least 4 h. At the end of the contact time, removed residual test materials by washing with warm water and made it dry carefully.

Described and scored the skin reactions for erythema and oedema according to the scoring system for each application site at each time interval. Recorded the reaction of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h after removal of the patches.

3. Results

Based on what observed:

The primary irritation index for the test article were calculated to be 0.

No abnormal clinical symptoms except skin reactions was found for all animals.

4. Conclusion

Under the conditions of this study, the test result showed that the test article did not induce skin irritation in rabbit.

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FINAL REPORT

Study Name: MedFort Face Mask- Skin Sensitization Test

Study Number: MED202007707-08-EN

Sponsor

Name: MEDFORT HEALTHCARE LIMITED

Address: SMILE CENTRE, 10-12 ON CHUEN STREET, FANLING, NEW TERRITORIES, HONG KONG

Testing Facility

Name: EPIN Suzhou Ltd.

Address: No.558 Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

SUMMARY

1. Purpose

To evaluate the potential skin irritation caused by the extraction of the test article extract contacting with the skin surface of rabbits.

2. Process Description

Test article was whole sampling by 3 cm^2: 1 mL, extraction condition was 37°C, 72 h. Extraction solvents were 0.9% sodium chloride (SC) and sesame oil (SO).

The rabbits used to conduct experiments were healthy and with intact skin. The fur on the back of the rabbit was clipped within 24 h before the test started, a sufficient area on both sides of the spine for application and observation of all test sites (approximately 10 cm×15 cm). The 2.5 cm×2.5 cm absorbent gauze patches were soaked with 0.5 mL extraction of test article or control and put the patches on the skin on each side of each rabbit directly, then wrapped the test sites with bandage (occlusive) for at least 4 h. At the end of the contact time, removed residual test materials by washing with warm water and made it dry carefully.

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3. Results

Based on what observed:

The primary irritation index for the test article were calculated to be 0.

No abnormal clinical symptoms except skin reactions was found for all animals.

4. Conclusion

Under the conditions of this study, the test result showed that the test article did not induce skin irritation in rabbit.

SGS

the lab (asia) ltd
testing, inspection, certification

CERTIFICATE OF COMPLIANCE

This is to certify that

The Cleanroom at

5/F,Smile Centre, 10-12 On Chuen Street
Fanling, N.T. , Hong Kong SAR

of Ownership

Medfort Healthcare Limited

Complies with the Acceptance Criteria of

BS EN ISO 14644-1: 2015: Class 8
(Ambient Particle Concentration)

As detailed in

Test Report No.: RP2100104

Date of Certification: 05/05/2021

Date of expiry: 05/05/2022

Date of issue: 10/05/2021

Certified by:

Ir Donney Man Wai Leung
Biosafety Consultant, MSc, MBA, BSc
NEBB Certified Cleanroom Professional

The Lab (Asia) Ltd. NEBB DONNEY M. LEUNG CERTIFICATION 3690 Exp. 3/31/22 Cleanroom Performance Testing

CETA National Board of Testing Donney Leung Registered Cleanroom Certification Professional for Sterile Compounding Facilities Expires 2021

The Lab (Asia) Ltd.

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MedFort® 醫堡 Healthcare Limited

香港優質標誌局
Hong Kong Q-Mark Council

香港工業總會
FHKI

No. ...C843...

LICENCE

to use the Hong Kong Q-Mark of the Federation of Hong Kong Industries

The Federation hereby grant to **Medfort Healthcare Limited** of **5/F., Smile Centre, 10-12 On Chuen Street, Fanling, N.T., Hong Kong.** and manufacturing address **5/F., Smile Centre, 10-12 On Chuen Street, Fanling, N.T., Hong Kong.** (hereinafter called the Licensee) the right and Licence to use the Hong Kong Q-Mark of the Federation in respect of the goods set out herewith which are produced by the Licensee in accordance with the appropriate recognized standard / specification referred to.

The Licence is granted subject to the Regulations approved by the Hong Kong Q-Mark Council of the Federation in respect of the Mark and to any Undertakings into which the Licensee has been required to enter with the Federation prior to the granting of this Licence and the Licensee hereby covenants with the Federation duly to observe and perform all the said Regulations and Undertakings.

Goods in respect of which the use of the Hong Kong Q-Mark is granted	Recognised standard / specification according to which the goods are to be produced
Product: 3-Ply Disposable Surgical Masks - **(Adult) – Level 3 – 10, 30 & 50pcs** **(Adult) – Level 2 – 30 & 50 pcs** **(Kids) -Level 3 – 30 & 50 pcs** **(Bulk/Individual Packing)** **Brand: Medfort** **This licence is valid for a period from 26th February 2021 to 30th November 2021 inclusively.**	**ASTM F2100-19e1 Standard Specification for Performance of Materials Used in Medical Face Masks ; GB15979 – 2002 "Hygienic Standard for Disposable Sanitary Products".**

Signed for and on behalf of the Federation

Chairman, Hong Kong Q-Mark Council

Date: 26 February 2021

MedFort® 醫堡 Healthcare Limited

Nelson Labs
A Sotera Health company

Sponsor:
MedFort Healthcare Limited
Smile Centre, 10-12 On Chuen Street,
Fanling, New Territories,
HONG KONG

Viral Filtration Efficiency (VFE) Final Report

Test Article:	MF-001
Study Number:	1316474-S01
Study Received Date:	02 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0007 Rev 16
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Test Area:	~40 cm^2
VFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	2.0 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.8 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Sarah Guzman electronically approved for — 03 Aug 2020 23:22 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent VFE (%)
1	>99.9
2	>99.9[a]
3	>99.9[a]
4	>99.9
5	99.9

[a] There were no detected plaques on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

$$\% VFE = \frac{C - T}{C} x\ 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Test Report

Date : 2020-06-19
No. : HC20060422

Applicant (Code:01325441) : MedFort Healthcare Limited
2/F Smile Centre
10-12 On Chuen Street
Fanling NT HK

Description of Sample(s) : One submitted sample said to be MedFort.
Country of Origin : HK

Sample(s) Received Condition(s): In intact original package under ambient temperature

Date Sample(s) Received : 2020-06-10

Date Tested : 2020-06-11 to 2020-06-18

Investigation Requested :
1. Total bacterial count
2. Total fungal count
3. Coliforms
4. Hemolytic *streptococcus*
5. *Pseudomonas aeruginosa*
6. *Staphylococcus aureus*

Conclusion(s) : The test results of the submitted sample **complied** with the limits of GB15979–2002 Hygienic Standard for Disposable Sanitary Products.

LEE Paul
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd.

Note: When a statement of conformity to a specification or standard is provided, the ILAC-G8 Guidance document (and/or IEC Guide 115 in the electrotechnical sector) will be adopted as a decision rule for the determination of conformity unless it is inherent in the requested specification or standard, or otherwise specified in the Report.

The Hong Kong Standards and Testing Centre Limited
10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong
Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group

Test Report

Date : 2020-06-19
No. : HC20060422

Method(s) Used:

GB15979–2002 Hygienic Standard for Disposable Sanitary Products, Appendix B.

Test Result(s):

Test Item(s)	MedFort	Microbial Limit (GB 15979-2002) *
1. Total bacterial count	<20 CFU/g	≤200 CFU/g
2. Total fungal count	<20 CFU/g	≤100 CFU/g
3. Coliforms	Not detected	Not detected
4. Hemolytic *streptococcus*	Not detected	Not detected
5. *Pseudomonas aeruginosa*	Not detected	Not detected
6. *Staphylococcus aureus*	Not detected	Not detected

Notes: - CFU/g denotes colony forming unit per gram
- < denotes less than
- ≤ denotes less than or equal to
- *These limits are only applicable to products that are in intact original package. Products that are already in use or have their package broken are not included.

***** End of Test Report *****

The Hong Kong Standards and Testing Centre Limited
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