

nt Beauty Gr Vincent Tse A Sotera Health company by Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited Room 2305, Apec Plaza, 49 Hoi Yuen Road Kwun Tong, Hong Kong **CHINA**

Sponsor:

Viral Filtration Efficiency (VFE) Final Report uty Group Company Limited (www.at

Test Article: Surgical Face Mask

Study Number: 1321260-S01 Study Received Date:

Nelson Laboratories, ar LLC mited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Testing Facility: Company Limited (www.artbeauty.com.l

6280 S. Redwood Rd.

Salt Lake City, UT 84123 U.S.A.

Standard Test Protocol (STP) Number: STP0007 Rev 16 Test Procedure(s): .hk)Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.ar

Deviation(s):

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 ФX174 was aerosolized using a nebulizer and delivered to the test article at a constant Limited (www.ai flow rate and fixed air pressure. The challenge delivery was maintained at 1.1 - 3.3 x 10³ 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 cm²

28.3 Liters per minute (L/min) VFE Flow Rate:

) Art Beauty Group Company Limited (www.ar 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours Conditioning Parameters:

Positive Control Average: 1.3 x 10³ PFU <1 PFU Negative Monitor Count:

o Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.ar MPS:

o Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.ar

.hk) Art Beauty Group Company Limited (www.artbeauty.com.h Company Limite Sean Shepherd electronically approved for

Study Director

20 Aug 2020 17:51 (+00:00)

Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Study Completion Date and Time

801-290-7500 nelsonlabs.com

sales@nelsonlabs.com

FRT0007-0001 Rev 16 Page 1 of 2 A Sotera Health company by Group Company Limited (www

Results:

	Results:			ited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group (www.artbeauty.c		
	Test Art	icle Number roup Company Lir	Perce	ent VFE (%)		
Company Limite	ed (www.artbeauty.com.hk	1		99.3		
		2		99.5	limited (www.ar	
	;	3		99.5 199.6 rt Beauty Group Company 99.8 99.6		
o Company Limite	ed (www.artbeauty.com.hk	4rt Beauty Group Company Em		99.8		
		5		99.6		

The filtration efficiency percentages were calculated using the following equation: Art Beauty Group Company Limited (www.ar (www.artbeauty.com.hk) Art Beauty Group Com

C = Positive control average

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

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Company Limited (www.artbeauty.cor

Sponsor: rt Beauty Gr Vincent Tse Art Beauty Group Company Limited Room 2305, Apec Plaza 49 Hoi Yuen Road Kwun Tong, Hong Kong, art Beauty Group C.**CHINA** Limited (www.ar

Latex Particle Challenge Final Report

17 Jul 2020 up Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Surgical Face Mask Test Article:

Study Number:

Study Received Date:

Testing Facility: Nelson Laboratories, LLC

6280 S. Redwood Rd.

Salt Lake City, UT 84123 U.S.A.

Standard Test Protocol (STP) Number: STP0005 Rev 08 Reauty Group Company Limited (www.al Test Procedure(s):

Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.c 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 Limited (www.at passed through the test article. The particles that passed through the test article were enumerated using Art Beauty Group Company Li 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 Limited (www.ai 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 Inside ompany Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.ar CFR Parts 210, 211 and 820.

Test Side:

Company Limited (www.artbeauty.com.harea Tested: 91.5 cm² 0.1 µm Particle Size:

> Laboratory Conditions: 21°C, 31% relative humidity (RH) at 1048; 21°C, 31% RH at 1210

0.047 company Limited (www.artbeauty.com.hk) Art Beauty Group Average Filtration Efficiency:

Standard Deviation:

o Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.a



ık)Art Beauty Group Company Limited (www.artbeauty.com.h McKenna Wild electronically approved for

Study Director

Curtis Gerow

07 Aug 2020 19:58 (+00:00) Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.a Study Completion Date and Time

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o Company Limited (www.artbeauty.com.hk)Art

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Results:

	Results:) Art Beauty Group Company	
	Test Article Number	Test Article Counts Lir	Average Control Counts	Filtration Efficiency (%)	
	ed (www.artbeauty.com.m.)	15	11,109	99.86	
	2	14	10,798	99.87	limited (WWW.
	3	10		99.87) Art Beaut 99.910 Company	
Company Limited	ed (www.artbeauty.com.hk) A	rt Beauty Group Company En	11,401	99.86	
	5	24	10,981	99.78	

- o Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.ar

- uity Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.ar FRT0005-0001 Rev 7



Sponsor: art Beauty Gr Vincent Tse Art Beauty Group Company Limited Room 2305, Apec Plaza 49 Hoi Yuen Road Kwun Tong, Hong Kong, Beauty Group CCHINA Limited (www.ar

Bacterial Filtration Efficiency (BFE) Final Report

Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.ar Surgical Face Mask Test Article:

Study Number: 1321259-S01

Study Received Date: 17 Jul 2020

Company Limited (www.arTesting Facility: Nelson Laboratories. LLC

6280 S. Redwood Rd.

Salt Lake City, UT 84123 U.S.A.

Standard Test Protocol (STP) Number: STP0004 Rev 18 Group Company Limited (www.ai Test Procedure(s): Company Limited(www.artbeauty.com.hk)Art Beauty Group Company Limited(www.artbeauty.com

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial counts ounts 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 10³ colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu m$. The aerosols were drawn through a sixstage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

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:

BFE Flow Rate:

28.3 Liters per minute (L/min) artbeauty.com.hk) Art Beauty Group Company Limited (www.ar Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours

~175 mm x ~170 mm Test Article Dimensions:

... ک. که **μm** D Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited(www.ar 2.9 x 10³ CFU Positive Control Average:



ık)Art Beauty Group Company Limited (www.artbeauty.com.h Company Limite Trang Truong electronically approved for

Study Director James Luskin 18 Aug 2020 04:53 (+00:00)

Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Study Completion Date and Time

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sales@nelsonlabs.com

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Study Number 1321259-S01

Bacterial Filtration Efficiency (BFE) Final Report

Results:

	Results:	(www.artbeauty.com.hk) Art Beauty Group Company Emilian	
	Test Article Number	Percent BFE (%)	
	ed (www.artbeauty.com.hk.) Art Beauty 5.55	99.2	
	2	99.5	
o Company Limite	3 ed (www.artbeauty.com.hk) A Beauty Group Company Limited 5	d(www.artbeauty.com.hk 9916 ' Beauty Group Company C	
	ed. (www.artbeauty.com.hk) A 4 Beauty Group Company Emilian	99.2	
	5	99.4	

The filtration efficiency percentages were calculated using the following equation: Art Beauty Group Company Limited (www.ar

Company Limited (www.a% $BFE = \frac{C + T}{C} \times 100$ T = Plate count total and the follows of the count total and the follows of the count total and the follows of the follo

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

o Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.artbeauty.com.hk)Art Beauty Group Company Limited (www.ar

Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk)