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



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

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

	Art Beauty Group Company Limited (www.artBeausy	
company Limited (www.artbeTest Article: Study Number:	Surgical Face Mask	
Study Number:	•	
Study Received Date:	16 Sen 2020	
Testing Facility:	Nelson Laboratories, LLC	
	6280 S. Redwood Rd., Limited (www.artbeauty	
	A Salt Lake City, UT 84123 U.S.A.	
company Limited(www.artheauty.com.hk) Company Limited(www.artheauty.com.hk)	Standard Test Protocol (STP) Number:	STP0036 Rev 15
	Customer Specification Sheet (CSS) Number:	
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 com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www 21 CFR Parts 210, 211 and 820.

Company Limite	Results:						
Jones	Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)	imited (www.
	1	3.1	3	<3	<6.0	<1.9	
Company Limit	2	3.1	3	<3	<6.0	<2.0	
	3	3.3	9	<3	<12.0	<3.6	imited (www.
	4	3.2	<3	<3	<5.9	<1.9	
Company Limit	5	3.1	<3	<3	<6.0	<1.9	
Jompany Envi	Recovery Efficiency			UTD ^a			1 (14040M

y.com.hk) Art Beauty Group Company ∟imi Note: The results are reported as colony forming units (CFU) per mask. < = No Organisms Detected UTD = Unable to Determine Beauty Group Company Limited (www

^a UTD due to zero count on the first rinse. An alternative method or inoculated product recovery efficiency is recommended.



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Study Number 1341861-S01 Microbial Cleanliness (Bioburden) of Medical Masks Final Report

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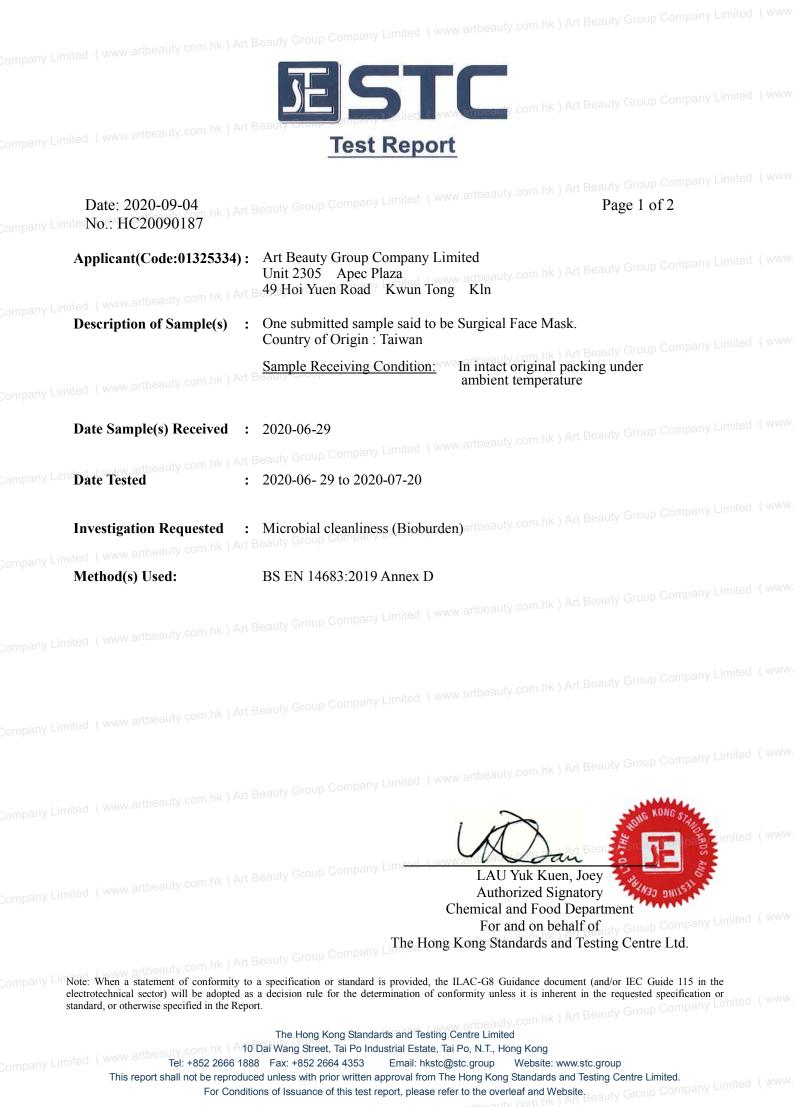
Method Suitability:

Organism	Percentage	/ Limited (www.
Bacillus atrophaeus	109%	

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden Limited (www 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.

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Procedure:		(
Positive Controls/Monitors: Extract Fluid: Company Limited (www.artbea Extract Fluid Volume: Extract Method:	Bacillus atrophaeus Peptone Tween [®] ed (www.artbeauty.com.hk) Art Beauty Group Company Limited ~300 mL Orbital Shaking for 15 minutes at 250 rpm	(
Plating Method: Agar Medium: Recovery Efficiency: ³ Aerobic Bacteria:	Membrane Filtration Tryptic Soy Agar Potato Dextrose Agar (www.artbeauty.com.hk.) Art Beauty Group Company Limited Exhaustive Rinse Method	(www.
		(www.
	Plates were incubated 5-7 days at 20-25°C, then enumerated.	
		(www.
		(www.
Company Limited (www.artbeau.y.c		(www.
		(www.
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801-290-7500 nelsonlabs.com sales		(www.
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Date: 2020-09-04) Art Beauty Group Company Limited (www.artbeauty.com.hk) Art Beauty Group Company Limited (www.artbeauty.com.hk)

No. : HC20090187

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Mean: 2 BS EN 14683:2019 Requirement: Octoberand Initial (www.artbeauty.com.hk.) Art Beauty Group Compare	
2 3.69 6 1.6 3 3.68 3 orn hk.) Art B0.8 y Group Compary 4 Art B 3.70 group Company Limited 0.8 (www.artbeauty.com.k.) 3.71 12 3.2 Mean: 2 BS EN 14683:2019 Requirement: artbeauty.com.k.) Art Beauty Group Company	
4 0.8 (www.artbeauty.com.tr.) 3.70 group Company Limited 0.8 (www.artbeauty.com.tr.) 3.71 12 3.71 12 3.2 Mean: 2 BS EN 14683:2019 Requirement: artbeauty Com.th.) Art Beauty Group Company	
mpany Limited (www.artbeauty.com.tk.) Art Beauty.com.tk.) Art Beauty Group Compar BS EN 14683:2019 Requirement:	
Mean: 2 BS EN 14683:2019 Requirement: art Beauty Group Compare	
Mean: 2 BS EN 14683:2019 Requirement: art Beauty Group Comparison	
BS EN 14683:2019 Requirement:	
The I are the Group Collapany Limited (Within a 200 CPUL)	
Type I $\leq 30 \text{ CFU/g}$	
Type II $\leq 30 \text{ CFU/g}$	
Type IIR ≤ 30 CFU/g Notes : CFU denotes Colony Forming Unit Image: Second	
Notes : CFU denotes Colony Forming Unit	

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The Hong Kong Standards and Testing Centre Limited

hk) A10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong

Company Limited (www.artbea Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group

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