NELSON LABORATORIES

Sponsor:
Healthy Breath Ltd
4D Pacific Rise, Mt Wellington
Auckland, 1060
NEW ZEALAND

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	MEO #3 - MEO #7
Purchase Order:	8347
Study Number:	973895-S01
Study Received Date:	29 Jun 2017
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: 800-STP0036 Rev 14 Customer Specification Sheet (CSS) Number: 201704310 Rev 01

Summary: The testing was conducted in accordance with EN 14683:2014, with the exception of bottle size, 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 validated 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	74.4	9[a]	15[a]	23.7	0.3
2	73.2	9[a]	6[a]	14.7	0.2
3	74.9	12[a]	21[a]	32.7	0.4
4	75.3	12[a]	3[a]	14.8	0.2
5	74.6	17[a]	3[a]	20.1	0.3
Recovery Efficiency			3.5%[b]		

< = No Organisms Detected
Note: The results are reported as colony forming units (CFU) per mask.
Note: Sample positive testing was performed using *Bacillus atrophaeus*. The test article was not inhibitory using this test method.
[a] Spreader. Count is considered a minimum estimate due to swarming of certain colonies on the membrane.
[b] Per AAMI/ANSI/ISO 11737-1, when a Recovery Efficiency is below 50 percent, additional testing should be considered to improve the efficiency.

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Study Director Robert J. Putnam, B.S.

20 JUL 2017
Study Completion Date

973895-S01

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween® with Sodium Chloride
Extract Fluid Volume:	~600 mL
Extract Method:	Orbital Shaking for 5 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Tryptic Soy Agar Sabouraud Dextrose Agar with Chloramphenicol
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 7 days at 20-25°C, then enumerated.