Nelson Labs
A Sotera Health company

Sponsor:
Kee Wei Wong
Safetyware Sdn. Bhd.
Plot 237, Lengkok Perindustrian Bukit Minyak 3
Bukit Minyak Industrial Estate
Simpang Ampat, Pulau Pinang, 14100
MALAYSIA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	1302
Study Number:	1318169-S01
Study Received Date:	08 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: 202004042 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	1	<3	<3	<6.2	<2.1
2	2	6	6	12.5	4.0
3	3	3	<3	<6.2	<2.1
4	4	<3	<3	<6.3	<2.0
5	5	<3	6	<8.7	<2.7
Recovery Efficiency	UTD[a]				

Note: The results are reported as colony forming units (CFU) per mask.
< = No Organisms Detected
UTD = Unable to Determine
[a] UTD due to zero count on the first rinse. An alternative method or inoculated product recovery efficiency is recommended.

Robert Putnam electronically approved — 31 Jul 2020 19:23 (+00:00)
Study Director Robert Putnam — Study Completion Date and Time

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	112%

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.