Declaration of Conformity

Elers Medical Finland Oy certifies that this product complies with requirements of Council directive 93/42/EEC.

Product	Procedure mask with earloop, type II, blue
Product code	M-102, M025
Medical device	Class I
Manufacturer	Elers Medical Finland Oy, PL 20, 00621 Helsinki, Finland
Specifications	Size: 17.5cm x 9.0cm Material: Non-woven, 3 PLY, Non-sterile, Latex free Bacterial filtration efficiency BFE ≥98 % Respiratory strength Delta P < 40 Pa/cm2 Microbial cleanliness Avg. ≤ 1.9 CFU/g
Medical Device standards	The medical device has been tested towards Medical face masks Requirements and test methods EN 14683: 2019. Test results are provided in annexes Annex 1. Bacterial Filtration Efficiency and Delta P Annex 2. Microbial cleanliness

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Nelson Labs.
A Sotera Health company

Sponsor:
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Pioneer Park, Ye'wang Road
Xintao City, Hubei Province, CN433000
CHINA

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

Test Article:	Face Mask 20191017CG
Study Number:	1235898-S01
Study Received Date:	28 Oct 2019
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 17
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:	~176 mm x ~156 mm
Positive Control Average:	2.5 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Curtis Herron For Janelle R. Bentz, M.S.
Study Director

16 Nov 2019
Study Completion Date

1235898-S01

Results:

Test Article Number	Percent BFE (%)
1	99.6
2	99.3
3	99.4
4	99.5
5	99.5

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.9	38.6
2	3.9	38.1
3	4.1	39.9
4	4.4	42.9
5	4.1	40.6

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

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Annex 2.

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CHINA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	Face Mask 20191017CG
Study Number:	1235897-S01
Study Received Date:	29 Oct 2019
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: 201905488 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	3.2	<3	<3	<6.1	<1.9
2	3.3	<3	<3	<5.9	<1.8
3	3.2	<3	<3	<5.9	<1.9
4	3.2	<3	<3	<6.1	<1.9
5	3.3	<3	<3	<5.9	<1.8
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 — 15 Nov 2019 20:29 (+00:00)
Study Director Robert Putnam — Study Completion Date and Time