PROTECTING YOUR BREATHING

מיגון מתח מאמים מבוקרים ותנאי הנשימה

Aviram F. Group

Industrial Manufacturing & Trading

LOGISTIC INFO:

MAGEN N95	Art# 1003 (M), 1005 (L)		
Pallet	**Master Pack**		**Inner Pack**
Size (Ti-6 Hi-3)	Size	Qty (of Inner Packs)	Size
100X120X173cm	32X58X48cm	20	28X11.8X10.5 cm
39.37X4.24X68"	12.6X22.83X18.9"		11.02X4.65X4.13"
Total of 9000 Per Pallet	Total of 500 Per Master		Total of 25 Per Pack

IQC

Institute of
Quality & Control

CERTIFICATE

NO. I20521K

This is to certify that
the Medical Devices Quality Management System of

Aviram F. Industries Ltd.

6 Harod St. Afula, Israel

Was audited by IQC and found to be
in compliance with the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

This certificate is valid for
the following scope of activities:

**Manufacturing of medical face masks,
respirator and surgical face mask**

This certificate is valid until:	07.06.2023
Certification cycle will end on:	07.06.2023
Date of first approval:	07.06.2020

This certificate is subject to the continuing satisfactory operation
of the Management System and periodic auditing by IQC

IQC

21.01.2021
Issue date

Nir Halpern, CEO

Institute of Quality & Control Ltd.
6 Ravnitzky St., Petah Tikva 4900617, Israel
Tel: 03-9313555, Fax: 03-9044406
E-Mail. info@iqc.co.il, www.iqc.co.il

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

MGMT. SYS.
RvA C 560

Nelson Labs.
A Sotera Health company

Sponsor:
Ghil Harly
Aviram f. Industries. Ltd.
Alon Tavor Industrial Zone Hollis Area
Afula, 1812000
ISRAEL

Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Report

Test Article:	Magen Mask 1003
Purchase Order:	637
Study Number:	1365146-S01
Study Received Date:	19 Nov 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: STP0145 Rev 05
Deviation(s):	None

Summary: This procedure was performed to evaluate the differential pressure of non-powered air-purifying particulate respirators in accordance with 42 CFR Part 84.180. The air exchange differential or breathability of respirators was measured for inhalation resistance using NIOSH procedure TEB-APR-STP-0007 and exhalation resistance with NIOSH procedure TEB-APR-STP-0003. The differential pressure technique is a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

The inhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial inhalation not exceeding 35 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

The exhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial exhalation not exceeding 25 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

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.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Natalie Brady electronically approved for	07 Dec 2020 16:53 (+00:00)
Study Director Adam Brigham	Study Completion Date and Time

Results:

Test Article Number	Inhalation Resistance (mm H_2O)	Exhalation Resistance (mm H_2O)
1	14.1	14.1
2	14.6	14.9
3	13.7	13.6

Test Method Acceptance Criteria: The resistance measurement for the reference plate must be within ± 3 standard deviations of the mean established in the control chart.

Procedure: A complete respirator was mounted to a test fixture comprised of a metal plate with an approximate 3.5 inch diameter hole in the center to allow airflow to reach the mask. The sample holder was assembled by placing a Plexiglas collar around the test fixture and topping with another metal disc with a 3.5 inch opening in the center. The sample holder is held tightly together with clamps and connected to an air source. The manometer is attached to the sample holder by a connection port on the Plexiglas collar.

Before testing, the manometer was zeroed and the back pressure in the sample holder checked and verified to be acceptable. Resistance measurements were taken with a manometer capable of measuring at least 6 inches of water. For inhalation testing, a negative airflow (vacuum) was applied. For exhalation testing, a positive airflow (compressed air) was used. Airflow was passed through the sample holder at approximately 85 ± 2 liters per minute (L/min).

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Alon Tavor Industrial Zone 5
Afula, Israel 1812000
ISRAEL

Synthetic Blood Penetration Resistance Final Report

Test Article:	Magen Mask 1003
Purchase Order:	206.70
Study Number:	1365147-S01
Study Received Date:	02 Dec 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: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

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.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.4°C and 21% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Leah Tiberius electronically approved for
Study Director — Curtis Gerow

21 Dec 2020 22:11 (+00:00)
Study Completion Date and Time

Nelson Labs.
A Sotera Health company

Sponsor:
Ghil Harly
Aviram f. Industries. Ltd.
Alon Tavor Industrial Zone Hollis Area
Afula, 1812000
ISRAEL

Flammability of Clothing Textiles Final Report

Test Article:	Magen Mask 1003
Purchase Order:	3965
Study Number:	1365148-S01
Study Received Date:	12 Nov 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: STP0073 Rev 07
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. 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 Article Side Tested:	Outside Surface
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds, IBE, or DNI
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

DNI = Test Article did not ignite
IBE = Test Article ignited, but extinguished

Curtis Gerow electronically approved — 15 Dec 2020 00:12 (+00:00)
Study Director Curtis Gerow — Study Completion Date and Time

Results: Testing was performed on samples as they were received. If refurbishing is needed, it is up to the sponsor to provide appropriate samples for testing before and after refurbishing. The test articles submitted by the sponsor achieved a Class 1 flammability rating.

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

Sponsor:
Ghil Harly
Aviram f. Industries. Ltd.
Alon Tavor Industrial Zone Hollis Area
Afula, 1812000
ISRAEL

Sodium Chloride (NaCl) Aerosol Test Final Report

Test Article:	Magen Mask 1003
Purchase Order:	3562
Study Number:	1365149-S01.1 Amended
Study Received Date:	19 Nov 2020
Study Completion Date:	15 Dec 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: STP0014 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 and TEB-APR-STP-0059 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized, and passed through the test article at a concentration not exceeding 200 mg/m^3. The initial airflow resistance and particle penetration for each respirator was determined.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

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.

Curtis Gerow electronically approved — 31 Dec 2020 23:48 (+00:00)
Study Director Curtis Gerow — Amended Report Date and Time

Sponsor:
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Alon Tavor Industrial Zone Hollis Area
Afula, 1812000
ISRAEL

Flammability of Clothing Textiles Final Report

Test Article:	Magen Mask 1003
Purchase Order:	819
Study Number:	1368141-S01
Study Received Date:	01 Dec 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: STP0073 Rev 07
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. 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 Article Side Tested:	Outside Surface
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds, IBE, or DNI
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

DNI = Test Article did not ignite
IBE = Test Article ignited, but extinguished

Sean Shepherd electronically approved for Adam Brigham
Study Director

19 Dec 2020 01:15 (+00:00)
Study Completion Date and Time

Results: Testing was performed on samples as they were received. If refurbishing is needed, it is up to the sponsor to provide appropriate samples for testing before and after refurbishing. The test articles submitted by the sponsor achieved a Class 1 flammability rating.

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

Sponsor:
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Alon Tavor Industrial Zone 5
Afula, 1812000
ISRAEL

Latex Particle Challenge Final Report

Test Article:	Magen N-95
Study Number:	1408011-S01
Study Received Date:	14 Apr 2021
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: STP0005 Rev 08
Deviation(s):	None

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 passed through the test article. The particles that passed through the test article were enumerated using 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 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 CFR Parts 210, 211 and 820.

Test Side:	Internal Layer
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	08 May 2021: 23.0°C, 21% relative humidity (RH) at 1549; 23.1°C, 21% RH at 1659 09 May 2021: 23.2°C, 21% RH at 1355, 23.2°C, 21% RH at 1511 10 May 2021: 21.9°C, 22% RH at 2048, 21.9°C, 22% RH at 2150, 22.1°C, 21% RH at 2235 13 May 2021: 22.5°C, 21% RH at 1940, 22.4°C, 21% RH at 2118, 22.0°C, 22% RH at 2208, 21.5°C, 22% RH at 2258 14 May 2021: 23.0°C, 21% RH at 1558, 22.9°C, 21% RH at 1733, 22.9°C, 21% RH at 1919, 22.5°C, 21% RH at 2109

Cameron Brierley electronically approved	19 May 2021 21:33 (+00:00)
Study Director Cameron Brierley	Study Completion Date and Time

Average % Filtration Efficiency: 99.9791%
Standard Deviation: 0.05141

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	1	12,836	99.9922
2	7	13,546	99.948
3	1	13,256	99.9925
4	4	13,110	99.969
5	5	13,201	99.962
6	7	13,007	99.946
7	9	12,602	99.929
8	7	12,158	99.942
9	6	12,152	99.951
10	2	11,763	99.983
11	<1[a]	11,477	>99.9971
12	<1[a]	12,604	>99.9974
13	<1[a]	12,896	>99.9974
14	<1[a]	12,928	>99.9974
15	<1[a]	13,371	>99.9975
16	<1[a]	12,854	>99.9974
17	<1[a]	12,675	>99.9974
18	2	13,610	99.985
19	2	12,480	99.984
20	2	11,029	99.982
21	2	11,897	99.983
22	2	11,851	99.983
23	<1[a]	11,652	>99.9971
24	1	11,175	99.9911
25	<1[a]	12,704	>99.9974
26	<1[a]	12,605	>99.9974
27	3	13,025	99.977
28	2	13,537	99.985
29	<1[a]	13,027	>99.9974
30	2	12,501	99.984
31	2	13,146	99.985

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
32	1	13,448	99.9926
33	1	12,288	99.9919
34	<1[a]	12,814	>99.9974
35	<1[a]	12,540	>99.9973
36	<1[a]	11,940	>99.9972
37	1	10,693	99.9906
38	4	12,632	99.968
39	2	11,644	99.983
40	2	11,946	99.983
41	<1[a]	12,590	>99.9974
42	1	12,905	99.9923
43	2	12,662	99.984
44	1	12,352	99.9919
45	<1[a]	12,864	>99.9974
46	<1[a]	14,082	>99.9976
47	<1[a]	13,016	>99.9974
48	<1[a]	11,761	>99.9972
49	1	12,944	99.9923
50	<1[a]	13,771	>99.9976
51	1	13,409	99.9925
52	<1[a]	12,970	>99.9974
53	1	12,795	99.9922
54	<1[a]	13,562	>99.9975
55	<1[a]	14,280	>99.9977
56	1	12,120	99.9917
57	1	12,011	99.9917
58	5	11,577	99.957
59	<1[a]	12,117	>99.9972
60	1	12,785	99.9922
61	<1[a]	12,387	>99.9973
62	2	12,452	99.984
63	<1[a]	12,564	>99.9973
64	<1[a]	12,756	>99.9974

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
65	1	14,184	99.9929
66	2	10,681	99.981
67	<1[a]	12,148	>99.9973
68	1	11,343	99.9912
69	<1[a]	11,167	>99.9970
70	1	10,826	99.9908
71	33	12,945	99.75
72	9	12,496	99.928
73	<1[a]	11,480	>99.9971
74	<1[a]	11,615	>99.9971
75	<1[a]	12,560	>99.9973
76	<1[a]	11,394	>99.9971
77	2	11,812	99.983
78	<1[a]	11,640	>99.9971
79	<1[a]	11,688	>99.9971
80	2	12,512	99.984
81	1	12,421	99.9919
82	<1[a]	12,061	>99.9972
83	2	13,228	99.985
84	1	12,944	99.9923
85	39	12,872	99.70
86	2	12,501	99.984
87	<1[a]	13,042	>99.9974
88	<1[a]	13,100	>99.9975
89	<1[a]	13,334	>99.9975
90	<1[a]	12,613	>99.9974
91	1	13,209	99.9924
92	<1[a]	14,038	>99.9976
93	27	12,529	99.78
94	30	12,664	99.76
95	1	11,181	99.9911
96	1	10,999	99.9909

[a] There were no detected particles penetrating this filter during testing.

Sponsor:
Ghil Harly
Aviram f. Industries. Ltd.
Alon Tavor Industrial Zone 5
Afula, 1812000
ISRAEL

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	Magen N-95
Study Number:	1408012-S01
Study Received Date:	03 May 2021
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 18
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.

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:	Side labeled “internal layer”
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	2.0 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.7 µm

Mikell Goldsberry electronically approved — 19 May 2021 23:14 (+00:00)
Study Director Mikell Goldsberry — Study Completion Date and Time

Results:
Batch 210422-1:

Test Article Number	Percent BFE (%)	Test Article Number	Percent BFE (%)
1	>99.9[a]	17	>99.9[a]
2	>99.9	18	>99.9
3	>99.9[a]	19	>99.9
4	>99.9[a]	20	>99.9[a]
5	>99.9[a]	21	>99.9[a]
6	>99.9[a]	22	>99.9
7	>99.9[a]	23	>99.9
8	>99.9[a]	24	>99.9[a]
9	>99.9[a]	25	>99.9[a]
10	>99.9[a]	26	>99.9
11	>99.9[a]	27	>99.9
12	>99.9[a]	28	>99.9[a]
13	>99.9[a]	29	>99.9[a]
14	>99.9	30	>99.9
15	>99.9[a]	31	>99.9[a]
16	>99.9[a]	32	>99.9[a]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Batch 210425-1:

Test Article Number	Percent BFE (%)	Test Article Number	Percent BFE (%)
1	>99.9[a]	17	>99.9[a]
2	>99.9	18	>99.9[a]
3	>99.9[a]	19	>99.9[a]
4	>99.9[a]	20	>99.9[a]
5	>99.9[a]	21	>99.9[a]
6	>99.9[a]	22	>99.9[a]
7	>99.9[a]	23	>99.9[a]
8	>99.9	24	>99.9[a]
9	>99.9	25	>99.9[a]
10	>99.9[a]	26	>99.9
11	>99.9[a]	27	>99.9[a]
12	>99.9[a]	28	>99.9
13	>99.9	29	>99.9[a]
14	>99.9[a]	30	>99.9[a]
15	>99.9[a]	31	>99.9[a]
16	>99.9	32	>99.9[a]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Batch 210427-1:

Test Article Number	Percent BFE (%)	Test Article Number	Percent BFE (%)
1	>99.9[a]	17	>99.9
2	>99.9[a]	18	>99.9[a]
3	>99.9[a]	19	>99.9[a]
4	>99.9[a]	20	>99.9
5	>99.9[a]	21	>99.9[a]
6	>99.9[a]	22	>99.9[a]
7	>99.9[a]	23	>99.9[a]
8	>99.9	24	>99.9[a]
9	>99.9[a]	25	>99.9
10	>99.9[a]	26	>99.9[a]
11	>99.9[a]	27	>99.9[a]
12	>99.9	28	>99.9[a]
13	>99.9[a]	29	>99.9[a]
14	>99.9	30	>99.9[a]
15	>99.9[a]	31	>99.9
16	>99.9[a]	32	>99.9[a]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

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

Aviram F. Group
Industrial Manufacturing & Trading

MAGEN