United States Corporate Office
SealPro Medical Corporation
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Asia Corporate Office
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21 Lam Hing Street
Kowloon Bay, Hong Kong

SealPro Medical Corporation attest that the product contained herein conforms to the Emergency Use Authorization as an “Appendix A: Authorization Imported, Non-NIOSH Approved Respirators Manufactured in China (Updated February 18, 2021)”

U.S. Food & Drug Administration’s segment for Personal Protective Equipment EUAs is attached, and available at the FDA.Gov:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixa

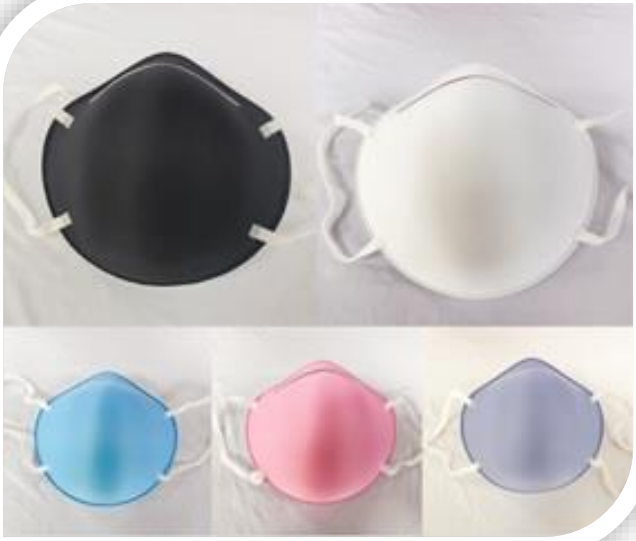
N95

3D PROTECTIVE MASK

+ GB2626-2019
+ Disposable, for single use only

SealPro Style: MA-08

SealPro SKU: S608



- 1st layer: Anti-droplet proof and waterproof fabrics
- 2nd layer: Dust prevention and fungi-proof non-woven fabric
- 3rd layer: Reinforcement layer of dust prevention and fungi-proofing non-woven fabric
- 4th layer: Fungi proof and antivirus melt-blown fabric
- 5th layer: Reinforcement layer of melt-blown fabric
- 6th layer: Reinforcement non-woven fabric
- 7th layer: Nano polyester fabric
- 8th layer: Comfortable moisture absorbent fabric

Eight layers of security

The outer layer is foam-proof, the inner layer is moisture-absorbing, comfortable and breathable

Size

- ☐ Small
- ☐ Medium
- ☐ Large
- ☐ Extra Large

Shelf Life 2 years

Color

- ☐ Black
- ☐ White
- ☐ Blue
- ☐ Pink
- ☐ Stone Blue

_____ Batch
___-____-_____ Manufactured
_____ Pieces this Case
_____ Quality Checked

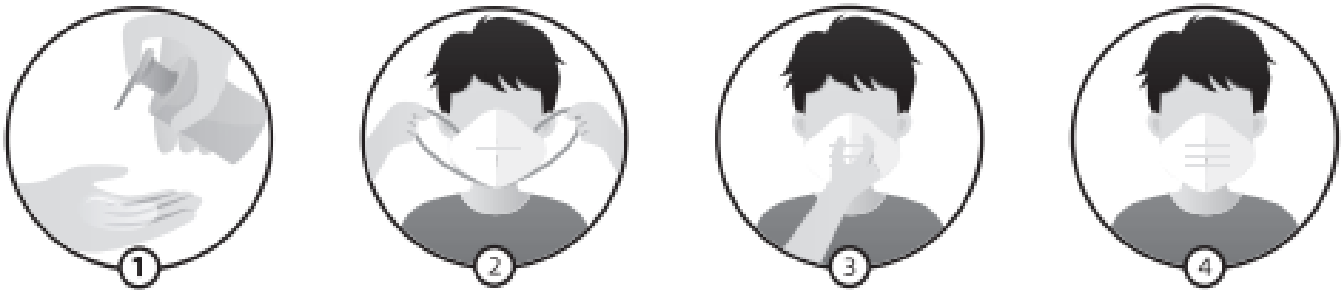
Huizhou City Lee Hing Textile Co. Ltd.
Nanya South Road, Shiwan Town, Boluo District, Huizhou City, Guangdong Province (0752-6573838)
Phone: (401) 753-7777

MADE IN CHINA

INSTRUCTIONS FOR USE

N95
3D PROTECTIVE MASK

Sealpro



Instructions:

1. Wash your hands before touching the mask.
2. Cover your mouth, nose and chin with the colored side facing outward.
3. Pinch the metal edge of the mask so it presses gently on your nose bridge.
4. Adjust your mask to your face without leaving gaps on the sides.

Warning:

1. The mask is not damaged or contaminated.
2. If you don't feel well, please leave the pollution area immediately.
3. If you can't breathe easily, please change the mask.
4. Cleaning or remould is not allowed.
5. People with respiratory diseases should use this mask with caution.
6. In the case of an allergic reaction, please remove the mask and seek medical advice

Personal Protective Equipment EUAs

Personal Protective Equipment refers to protective clothing, helmets, gloves, face shields, goggles, respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.

To help address concerns about availability during the COVID-19 pandemic, the FDA has issued EUAs for certain PPE products including face shields, other barriers, and respiratory protective devices such as respirators. Additionally, the FDA has issued recommendations and policies about PPE which can be found here: Recent Final Medical Device Guidance Documents.

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA, including an Interactive Review Template For Non-IVD Products. Additionally, the FDA has posted a Surgical Masks EUA Template for Addition to Appendix A of the Surgical Mask Umbrella EUA.

Table of Personal Protective Equipment (PPE) EUAs

Appendix A: Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China (Updated February 18, 2021)

The table below includes a list of non-NIOSH-approved respirator models manufactured in China that are authorized by this Umbrella EUA for emergency use during the COVID-19 public health emergency.

As stated in the EUA, authorized respirators are authorized for use by healthcare personnel in healthcare settings in accordance with the CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators.

Search: Regina Miracle

Show All entries

Manufacturer	Respirator Model(s)	Instructions for Use
Regina Miracle (Shenzhen) Ltd.	RM2020 MA-08	

Showing 1 to 1 of 1 entries (filtered from 167 total entries)

Previous 1 Next

Manufacturer	Respirator Model(s)
Regina Miracle (Shenzhen) Ltd.	RM2020 MA-08

Nelson Labs
A Sotera Health company

Sponsor:
Zhifeng Liang
Regina Miracle (Shenzhen) Ltd.
No.2 Cengyao Industrial Estate,
Yulu, Yutang, Guangming New District,
Shenzhen,
CHINA

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

Test Article:	N95 TECT Respirator Style No: RM2020 MA-08
Purchase Order:	20-698A
Study Number:	1338709-S01.2 Amended
Study Received Date:	04 Sep 2020
Study Completion Date:	30 Sep 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

Sean Shepherd electronically approved for Curtis Gerow
Study Director

15 Oct 2020 16:32 (+00:00)
Amended Report Date and Time

Results:

Test Article Number	Inhalation Resistance (mm H_2O)	Exhalation Resistance (mm H_2O)
1	13.4	14.0
2	13.7	14.2
3	13.1	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).

Amendment Justifications:

.2 Amended: At the request of the sponsor, the test article was updated from "N95 TECT Respirator Model: RM220 MA-26" to "N95 TECT Respirator Style No: RM2020 MA-08" Additionally, the sponsor information was updated

.1 Amended: At the request of the sponsor, the test article was changed from "Particle Filtering Half Mask Model: RM2020 MA-26" to "N95 TECT Respirator Model: RM2020 MA-26"

Nelson Labs
A Sotera Health company

Sponsor:
Zhifeng Liang
Regina Miracle (Shenzhen) Ltd.
No.2 Cengyao Industrial Estate, Yulu, Yutang
Guangming New District
Shenzhen, China

Sodium Chloride (NaCl) Aerosol Test Final Report

Test Article:	N95 TECT Respirator Style No: RM2020 MA-08
Purchase Order:	20-698A
Study Number:	1338708-S01
Study Received Date:	04 Sep 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.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Natalie Brady electronically approved for — 28 Oct 2020 19:40 (+00:00)
Study Director Curtis Gerow — Study Completion Date and Time

Results: The NIOSH N95 filter efficiency as stated in 42 CFR Part 84.181 is a minimum efficiency for each filter of ≥95% (≤5% penetration). The test articles submitted by the sponsor conform to the NIOSH N95 criteria for filter efficiency.

Test Article Number	Corrected[a] Initial Airflow Resistance (mm H_2O)	Maximum Particle Penetration (%)	Filtration Efficiency (%)
1	16.2	0.045	99.955
2	15.9	0.056	99.944
3	14.8	0.073	99.927
4	17.4	0.064	99.936
5	19.1	0.083	99.917
6	18.0	0.067	99.933
7	17.7	0.041	99.959
8	16.5	0.114	99.886
9	16.9	0.056	99.944
10	16.5	0.083	99.917
11	16.3	0.114	99.886
12	17.2	0.030	99.970
13	17.4	0.036	99.964
14	16.6	0.059	99.941
15	16.8	0.043	99.957
16	17.4	0.047	99.953
17	17.9	0.045	99.955
18	17.7	0.050	99.950
19	17.2	0.049	99.951
20	17.3	0.082	99.918

[a] The final airflow resistance value for each test article was determined by subtracting out the background resistance from the system.

Test Method Acceptance Criteria: The filter tester must pass the "Tester Set Up" procedure. The airflow resistance and particle penetration of the reference material must be within the limits set by the manufacturer.

Filter Test Procedure: Prior to testing, respirators were taken out of their packaging and placed in an environment of 85 ± 5% relative humidity (RH) and 38 ± 2.5°C for 25 ± 1 hours.

The filter tester used in testing was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produces a particle size distribution with a count median diameter of 0.075 ± 0.020 microns (µm) and a geometric standard deviation not exceeding 1.86 µm. The mass median diameter was approximately 0.26 µm, which is generally accepted as the most penetrating aerosol size. The reservoir was filled with a 2% NaCl solution and the instrument allowed a minimum warm-up time of 30 minutes. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 psi. The NaCl aerosol generator pressure was set to approximately 30 psi and the make-up airflow rate was set to approximately 70 liters per minute (L/min).

The NaCl concentration of the test aerosol was determined in mg/m^3 by a gravimetric method prior to the load test assessment. An entire respirator was mounted on a test fixture, placed into the filter holder, and the NaCl aerosol passed through the outside surface of the test article at a continuous airflow rate of 85 ± 4 L/min. In accordance with NIOSH policy, three respirators were challenged until 200 ± 5 mg of NaCl had contacted each test article. Based upon the load pattern of NIOSH Type 2, the initial penetration reading of the remaining 17 respirators was recorded.