



**N95 Mask from Avery Dennison Medical*
Surgery Certifications**

**Secure Fit ~ Comfort ~ Breathability ~ Ease of Use
Country of Origin: U.S.A. – Manufactured in Ohio**

- NIOSH N95 Certified, US Manufactured
- Medical grade materials; Gentle adhesive
- Meets ASTM F2101 Standard for Bacterial and Virus Filtration Efficiency
- Meets ASTM F1862 Standard for Synthetic Blood Pressure Resistance
- Meets 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles
- Meets ASTM F2299 Standard for Latex Particle Challenge
- Passes 3-hr Dry Spore Test (STP 200305804-01)
- Meets MIL-M-36945C for Differential Pressure
- Filtration during inhaling and exhaling
- Possibly maintains cooler temperatures around wear surface

***[Manufactured for Avery Dennison Medical by Global Safety First, LLC under TC#84A-8133]**



N95 ASTM Level 2 Filtering Facepiece Respirators (FFR)

Product Overview:

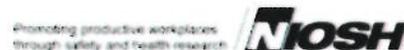
- Manufacturer: Global Safety First
- Model Numbers:
 - N1901S, N1901L, N1901XL: Synthetic rubber
 - N1906S, N1906L, N1906XL: Gentle Acrylic adhesive
- NIOSH Reference: TN-22414
- NIOSH Approval Number: TC-84A-8133
- Country of Origin: United States

NIOSH Testing:

Test Description	STP Number	Result
Exhalation Resistance Test	TEB-APR-STP-0003	Pass
Inhalation Resistance Test	TEB-APR-STP-0007	Pass
Evaluation of Novel Head Harness	CVB-63C-STP-0015	Pass
Sodium Chloride (NaCl) N95 Test	TEB-APR-STP-0059	Pass

Regulatory Status:

1. Department of Health & Human Services-National Institute for Occupational Safety & Health (NIOSH) Approval -18May2020 (Attachment 1). The screen shot below can be found at:
https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1-g.html



NIOSH-Approved N95 Particulate Filtering Facepiece Respirators

Updated May 26, 2020

Manufacturers Listed Alphabetically – G

The N95 respirator is the most common of the seven types of particulate filtering facepiece respirators. This product filters at least 95% of airborne particles but is not resistant to oil.

This web page provides a table of NIOSH-approved N95 respirators, listed alphabetically by manufacturer. You can select a particular manufacturer by clicking on the first letter of their name on the index below.

There are some products that are approved by NIOSH as an N95 respirator and also cleared by the Food and Drug Administration (FDA) as a surgical mask. These products are referred to as **Surgical N95 Respirators**. [View a definition of Surgical N95 Respirators](#). For your convenience the Surgical N95 Respirators are indicated with the **Model Number/Product Line in bold text followed by (FDA)**. If you have a product you believe is NIOSH-approved and FDA-cleared that does not appear on this list, you will need to check with CDC to determine if NIOSH-approved at 1-800-CDC-INFO (1-800-232-4636) and the FDA Center for Devices and Radiological Health at 1-800-638-2041 for verification of clearance. [View a comprehensive table of Surgical N95 Respirators](#).

[Global Safety First](#)

610-240-0909

N1901L

84A-

No

[All Models](#)

N1901X

8133

[\[PDF - 486 KB\]](#)

N1902L

N1902X

2. On May 18, 2020, the Department of Health & Human Services-National Institute for Occupational Health (NIOSH), granted Global Safety First the approval to add the “S” (small size) masks along with the introduction to alternative adhesives which is identified internally by N1903 and N1906 (Attachment 2)



3. On March 28, 2020, the FDA issued a EUA (Attachment 3) to authorize the emergency use of:

safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the March 27, 2020 letter in its entirety⁵ with the amendment⁶ incorporated to authorize the emergency use of:

(1) Non-powered air-purifying particulate FFRs and reusable respirators such as elastomeric half and full facepiece respirators, approved by NIOSH in accordance with 42 CFR Part 84 and listed on the [NIOSH Certified Equipment list \(CEL\) for non-powered air purifying respirators with particulate protection](#);

- The EUA can be found at: <https://www.fda.gov/media/135763/download>
- Using this link, Global Safety First can be found on page 105, approval number 8133.

The National Personal Protective Technology Laboratory (NPPTL)



84A	8133	Global Safety First	N1900 Series N95 Filtering Facepieces with Novel Head Suspension, Air Purifying Respirator	Filtering Facepiece
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4. On May 7, 2020, the FDA re-issued an updated EUA that has removed certain N95 mask manufacturers from the approved list. This does not affect Global Safety First due to the fact the updated EUA is for N95 masks made in China. The Appendix A associated with this EUA only lists approved masks made in China. The link to the Appendix can be found here: <https://www.fda.gov/media/136663/download>.



Conclusion:

Although the above FFR does not have FDA approval, the FDA has authorized the use through the published EUA because the FFR have met the criteria to be placed on the approved CDC-NIOSH list.

Kelli R Jonas

Kelli Jonas
Vice President, Quality Assurance/Regulatory Affairs



DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-22414
Mfr. Reference: GSFN1900b

Centers for Disease Control
and Prevention (CDC)

National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
626 Cochran's Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

March 6, 2019

Mr. Brian Weller
President
Global Safety First
Paoli Executive Green 1, Suite 200
41 Leopard Road
Paoli, Pennsylvania 19301

Dear Mr. Weller:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted July 6, 2018. This request was for approval of the N1900 series of air-purifying filtering facepiece respirators (part numbers N1901L, N1901X, N1902L and N1902X) for protection against particulates at N95 filter efficiency level. The complete respirator configurations are detailed on assembly matrix, file name *N1900AMc.xls*, revision c, dated: 02/26/19.

The site qualification conducted at your facility in Westminster, Maryland on November 28, 2018, and your responses to the Corrective Action Requests (CARs), specifically CARs 22414-01 through 22414-05 have been accepted and all the nonconformance issues related to the site qualification have been resolved.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired to be produced in languages other than English. Approval number TC-84A-8133 has been assigned. This respirator is approved for protection against particulates at N95 filter efficiency level.

NIOSH has also reviewed the quality manual file name *N1900QMa.doc* presented and finds that this manual meets or exceeds the minimum technical requirements for quality assurance plans as outlined in Title 42, *Code of Federal Regulations (CFR)*, Part 84.41(a) and, on the basis of this review, this quality manual is accepted.

The final respirator approval label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

Page 2 – Brian Weller– TN-22414

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Jeff Peterson', with several long, sweeping horizontal lines extending to the right.

**Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch**

Enclosures



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control
and Prevention (CDC)

NIOSH Reference: TN-23898
Mfr. Reference: GSFN1900e

National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
626 Cochran Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051
May 18, 2020

Mr. John Schwind
Global Safety First
50 Curtis Avenue
Manasquan, New Jersey 08736

Dear Mr. Schwind:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted May 11, 2020. This request was for extension of approval TC-84A-8133 to add small size versions (part numbers N1901S and N1902S) to GSF N1900 series air-purifying filtering facepiece respirators. The only difference in model numbers is the color of the respirator assembly. This request is due to the current COVID-19 Public Health Emergency. The complete respirator configurations are detailed on assembly matrix file name *N1900AMe.xls*, revision e, dated: 05/15/2020.

In addition, four alternative adhesives are introduced, and the Process Quality Plan is updated to ensure the proper steps are in place for each selected adhesive. The user instructions are updated to include the additional size.

This request is granted. Extension of approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired to be produced in languages other than English.

The final respirator approval label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to these approvals are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assemblies consist of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

Page 2- Mr. John Schwind- TN-23898

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely,

Jeffrey A. Peterson -S

Digitally signed by
Jeffrey A. Peterson -S
Date: 2020.05.18
16:11:19 -04'00'

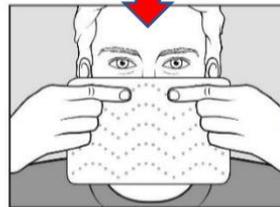
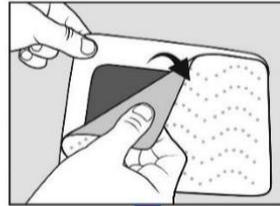
Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosures



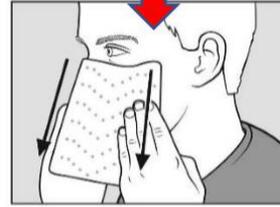
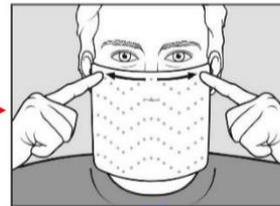
N95 From Avery Dennison Medical

1 Prepare



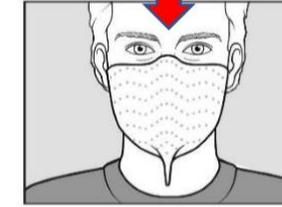
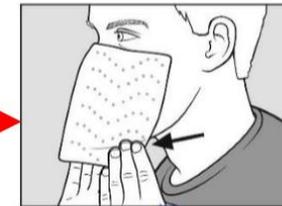
Critical Point This Step
Press down deep around your nose with your fingertips BEFORE sliding your fingertip out towards your ears.

2 Position



Critical Point This Step
When sliding fingertips outwards under the eyes (top pic) Draw a straight horizontal line across... no downward motion.

3 Secure



Critical Point This Step
Ensure all areas below the chin and nose bridge are well sealed for secure fit.

****Tip: Practice proper fit of the mask by standing in front of a mirror****

info@gelsafetyolutions.com



Product Overview

- N95 Mask is unique because it can form a tight seal around the face
- Masks provide maximum protection while allowing filtration during inhalation and exhalation



CONTAINS NO METAL

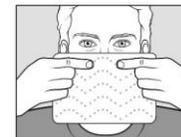
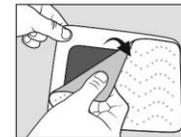
info@gelsafetyolutions.com

Product Overview

- Masks are virtually weightless, eliminating tight straps, ties, and uncomfortable metal nose clips
- Masks are designed with a very low breathing resistance and may help maintain a cooler temperature than other similar masks



1 Prepare



2 Position



3 Secure





Avery Dennison Medical Mask Difference

Current Masks: Seals are not tight, regardless of the "fitting" and can come with an extra cost.

Avery Dennison Medical Masks: The complete adhesive perimeter offers a tight seal providing maximum protection.

Current Masks: A metal nose clip compensates for the lack of a proper seal.

Avery Dennison Medical Masks: A comfortable design that helps provide secure fit and not interfere with user's loupes.

Current Masks: Tight straps and ties put pressure on the face and get caught in the hair.

Avery Dennison Medical Masks: Evaluations, such as those from Matt Petridies PA-C (next page), report he sometimes doesn't even know it is on.

Current Masks: Many masks fit just below the mouth.

Avery Dennison Medical Masks: Mask extends further on the face and form fits around chin and cheeks.

Current Masks: Feel like you're in a warm stuffy room making it hard to breathe.

Avery Dennison Medical Masks: The low breathing resistance allows filtration during inhalation and exhalation and may help maintain a cooler temperature.

Current Masks: Today's N95's are stiff, bulky, and boast of 40-year-old design features!

Avery Dennison Medical Masks: Mask is virtually weightless, forms a comfortable seal and is easy to use.



FAQs

- N95 Respirator
- NIOSH N95 Certified
- Country of Origin: USA Manufactured in Ohio
- Medical grade materials; Gentle adhesive
- Filtration during inhaling and exhaling
- May help maintain cooler temperatures around wear surface
- Orders placed expect a 3-6-week lead time
- A comfortable design that helps provide secure fit and not interfere with user's loupes
- Unable to be sterilized for multiple uses