NPPTL COVID-19 Response: Beyond Shelf Life/Stockpiled Respirator Assessment

Manufacturer: TrioMed Innovations Corp.
Model Tested: 112410 (TC-84A-5200)
Date Tested: September 11, 2020
Report Prepared: September 11, 2020

These findings pertain to the TrioMed Innovations Corp., model 112410 (TC-84A-5200) submitted for testing and may not be applicable to other stockpile facilities and/or under different environmental storage conditions. The maximum and minimum filter efficiency was 99.87% and 99.66%, respectively. All twenty respirators measured more than 95% filter efficiency.

NIOSH regulation sets the minimum quality and performance requirements for the approval of respirators (42 CFR 84). **NIOSH does not have requirements for shelf life or storage conditions for particulate-only APRs.** The approval holder (i.e. the entity that is granted the approval from NIOSH) is responsible for understanding how their products' design or performance may be affected by various use or storage conditions and must provide instruction for establishing the proper use, storage, and maintenance procedures for their approved products, which may include designating a shelf life. FFR or particulate filter packaging (such as the box) often includes NIOSH-approved user instructions, label information, and recommendations on shelf life. Additionally, some approval holders also disseminate recommendations related to storage and shelf life through resources such as user and web notices. The respirators tested in this study were generally not designed for long-term storage.

Based on research conducted by NIOSH and this limited testing, NIOSH does not have enough information to definitively know the level of protection that may be provided by respirators that 1) are stored for prolonged periods of times; 2) are stored under various storage conditions; or 3) have exceeded the approval holder's designated shelf life. Users of respirators that have exceeded the designated shelf life should be forewarned to avoid a false sense of confidence; these devices may not provide the same level of protection as those that have not exceeded the designated shelf life. We recommend contacting the approval holder(s) of the respirators in the stockpile with specific questions regarding the use of product beyond the manufacturer- designated shelf life.

The results provided in this letter are specific to the subset of NIOSH-approved N95s, past their designated shelf life, that were provided to NPPTL for evaluation.

These results will be added to the CDC guidance for Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life.

Evaluation of Stockpiled and Beyond Manufacturer-Designated Shelf Life N95s

NPPTL
National Personal Protective Technology Laboratory

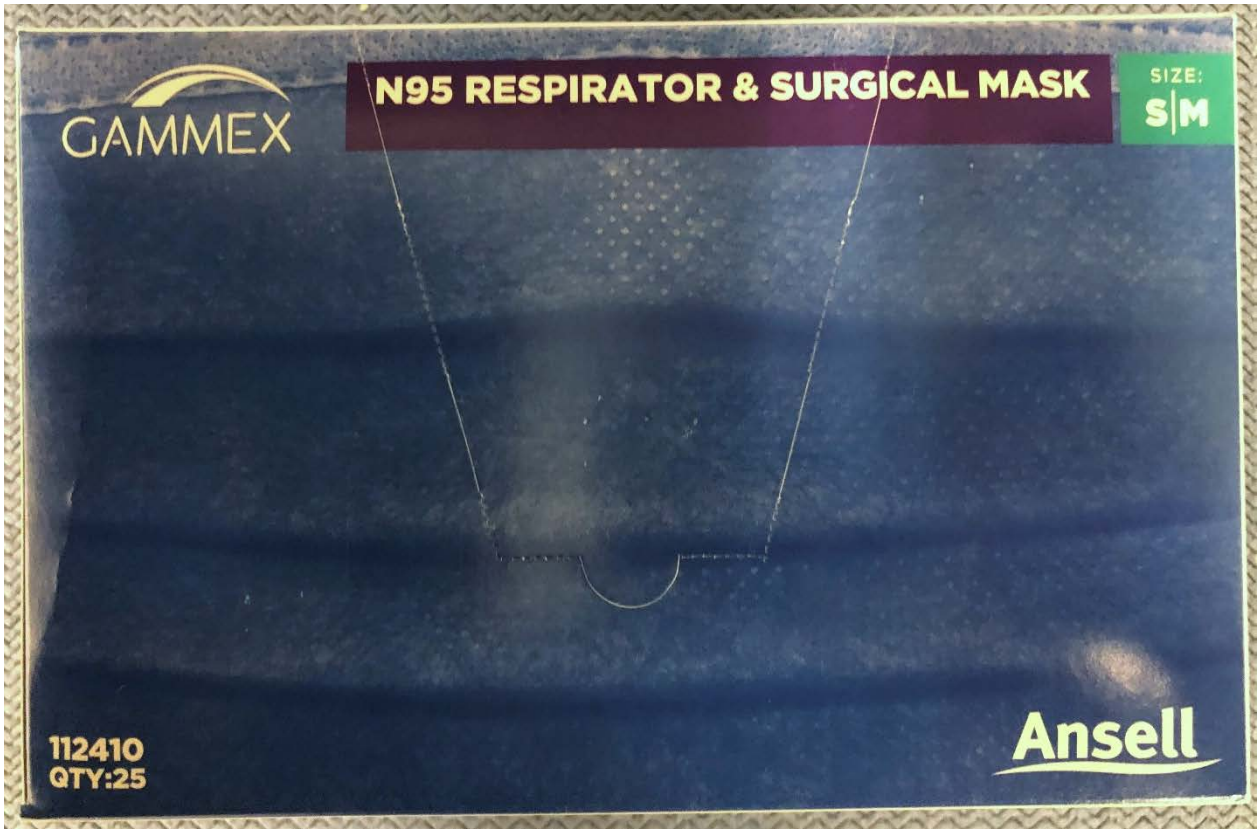
Test: TEB-APR-STP-0059

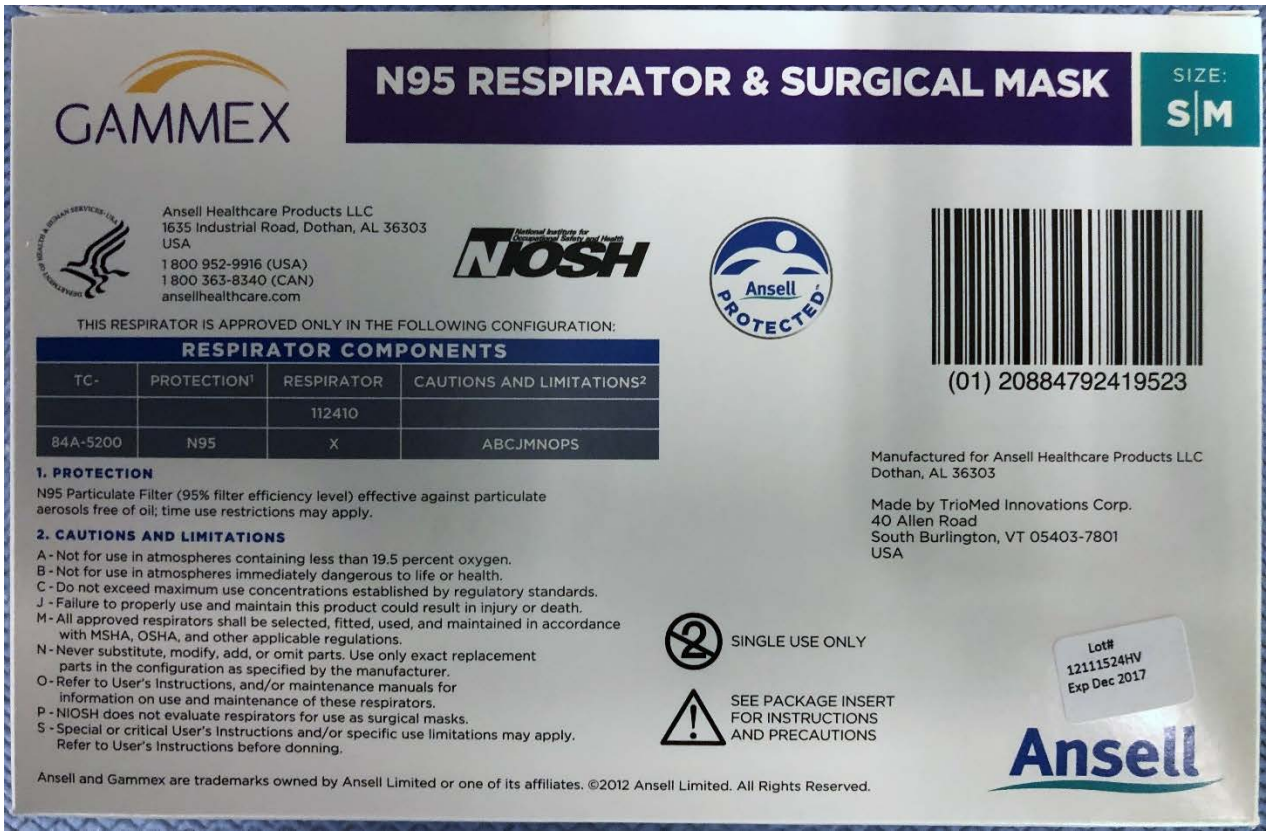
Manufacturer: TrioMed Innovations Corp.

Item Tested: 112410 (TC-84A-5200)

Expiration Date: 12/2017 **Manufacture Date:** None Provided

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	13.3	0.21	0.21	99.79
2	85	15.8	0.34	0.34	99.66
3	85	13.2	0.13	0.13	99.87
4	85	14.4	0.22	0.22	99.78
5	85	15.4	0.20	0.20	99.80
6	85	13.2	0.18	0.18	99.82
7	85	15.0	0.21	0.21	99.79
8	85	16.2	0.23	0.23	99.77
9	85	13.3	0.17	0.17	99.83
10	85	17.9	0.26	0.26	99.74
11	85	14.8	0.30	0.30	99.70
12	85	13.1	0.14	0.14	99.86
13	85	16.3	0.28	0.28	99.72
14	85	14.4	0.26	0.26	99.74
15	85	14.7	0.18	0.18	99.82
16	85	15.1	0.30	0.30	99.70
17	85	14.4	0.30	0.30	99.70
18	85	13.7	0.21	0.21	99.79
19	85	13.7	0.19	0.19	99.81
20	85	13.2	0.20	0.20	99.81
Minimum Filter Efficiency: 99.66%				**Maximum Filter Efficiency: 99.87%**	


GAMMEX
N95 RESPIRATOR & SURGICAL MASK
SIZE:
S|M
112410
QTY:25
Ansell


GAMMEX
N95 RESPIRATOR & SURGICAL MASK
SIZE:
S|M
Ansell Healthcare Products LLC
1635 Industrial Road, Dothan, AL 36303
USA
1 800 952-9916 (USA)
1 800 363-8340 (CAN)
ansellhealthcare.com
NIOSH
Ansell PROTECTED
(01) 20884792419523
THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:
RESPIRATOR COMPONENTS
TC- | PROTECTION[1] | RESPIRATOR | CAUTIONS AND LIMITATIONS[2]
112410
84A-5200 | N95 | X | ABCJMNOPS
1. PROTECTION
N95 Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply.
2. CAUTIONS AND LIMITATIONS
A - Not for use in atmospheres containing less than 19.5 percent oxygen.
B - Not for use in atmospheres immediately dangerous to life or health.
C - Do not exceed maximum use concentrations established by regulatory standards.
J - Failure to properly use and maintain this product could result in injury or death.
M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
P - NIOSH does not evaluate respirators for use as surgical masks.
S - Special or critical User's Instructions and/or specific use limitations may apply. Refer to User's Instructions before donning.
Manufactured for Ansell Healthcare Products LLC
Dothan, AL 36303
Made by TrioMed Innovations Corp.
40 Allen Road
South Burlington, VT 05403-7801
USA
SINGLE USE ONLY
SEE PACKAGE INSERT FOR INSTRUCTIONS AND PRECAUTIONS
Lot# 12111524HV
Exp Dec 2017
Ansell
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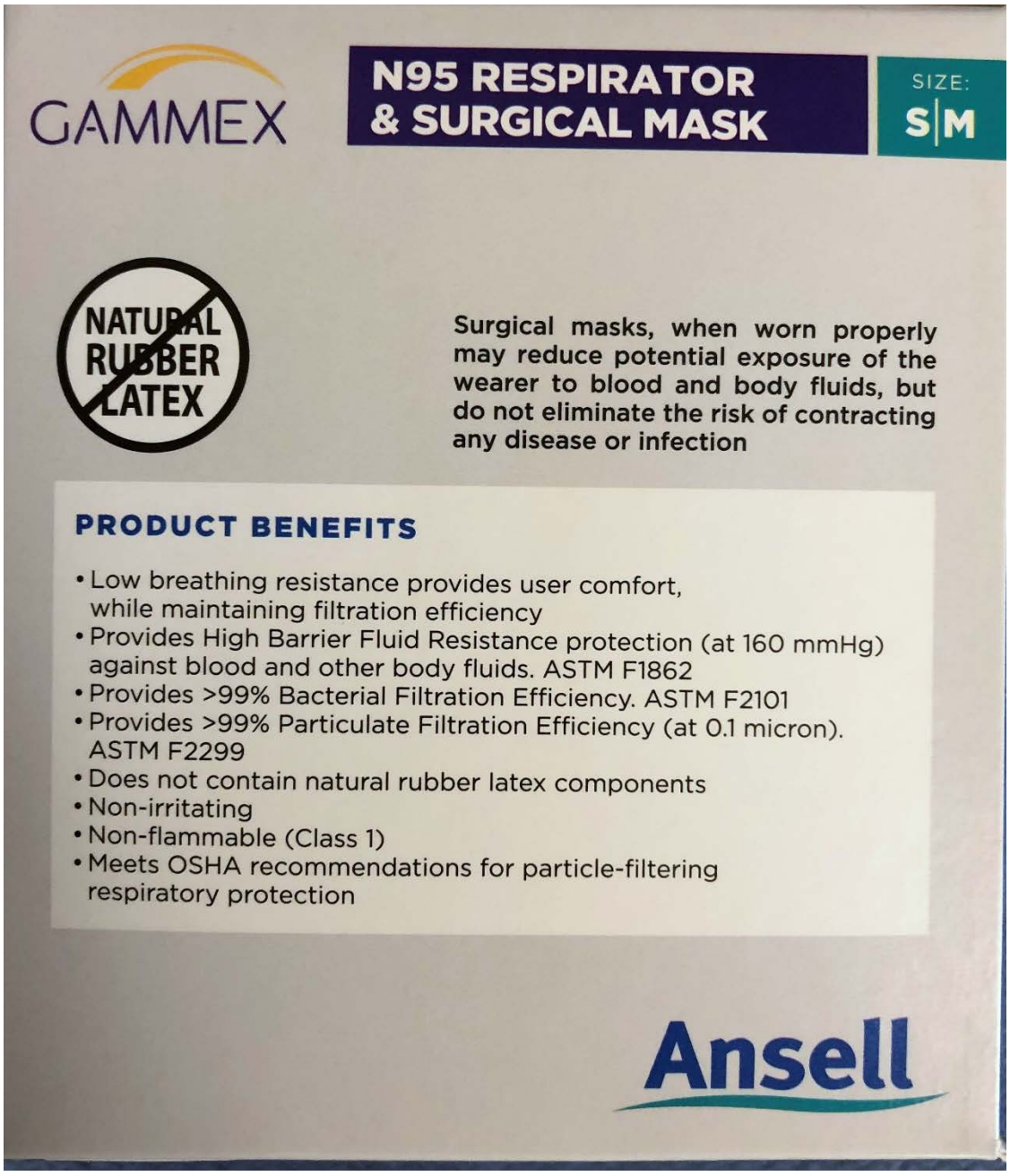
GAMMEX
N95 RESPIRATOR & SURGICAL MASK
SIZE:
S|M
Ansell
PROTECTED
Ansell


GAMMEX
N95 RESPIRATOR
& SURGICAL MASK
SIZE:
S|M
MADE IN USA
112410
QTY:25
INTENDED USE AND INDICATIONS
The 112410 (S/M) N95 Respirator and Surgical Mask is a single use disposable device intended to protect healthcare workers and patients from the transfer of microorganisms, blood, body fluids, and airborne particulate materials. The respirator/surgical mask may be used during medical, surgical and dental procedures, and may also be used as an isolation mask.
Ansell


GAMMEX
N95 RESPIRATOR & SURGICAL MASK
SIZE: S|M
NATURAL RUBBER LATEX
Surgical masks, when worn properly may reduce potential exposure of the wearer to blood and body fluids, but do not eliminate the risk of contracting any disease or infection
PRODUCT BENEFITS
• Low breathing resistance provides user comfort, while maintaining filtration efficiency
• Provides High Barrier Fluid Resistance protection (at 160 mmHg) against blood and other body fluids. ASTM F1862
• Provides >99% Bacterial Filtration Efficiency. ASTM F2101
• Provides >99% Particulate Filtration Efficiency (at 0.1 micron). ASTM F2299
• Does not contain natural rubber latex components
• Non-irritating
• Non-flammable (Class 1)
• Meets OSHA recommendations for particle-filtering respiratory protection
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GAMMEX

N95 RESPIRATOR & SURGICAL MASK

112410 SIZE: S|M

112411 SIZE: M|L

Donning and Fitting

1. Pre-shape the nose clip at the top center of the respirator as it will rest over the bridge of the nose.
2. Hold the respirator in one hand with straps dangling beneath and the inside of the respirator facing upward.
3. Hold the respirator against the face, pull the top head strap over the head and position it above the ears. Pull the lower head strap over the head and position it around the neck below the ears.
4. Hold the nose clip while pulling down on the bottom of the respirator to open the pleats and position the bottom of the respirator just beneath the chin. Press nose clip to form along the nose on both sides until a good seal is established.
5. FIT CHECK: Place both hands on the edges of the respirator, being careful not to disturb the position of the respirator. Exhale sharply to detect any leakage. If you detect air leaks, re-position or re-don the mask as needed to achieve a satisfactory seal.

Removal of Respirator

After use, microorganisms may be present on the exterior surface of any mask or respirator. Remove the used protective device carefully, avoiding selfcontamination, and immediately sanitize hands. Disinfect surfaces in the immediate area where droplets of microorganisms may have fallen.

Important

If you cannot achieve a satisfactory fit, do not enter the contaminated area. Failure to follow all instructions and limitations can seriously reduce the effectiveness of any respirator and could lead to illness, injury or disease. Respirators cannot completely eliminate the risk of contracting disease or infection.

Special User's Instructions

Model 112410 and 112411 Filtering Facepiece have been manufactured by approval holder TrioMed Innovations Corp for Ansell under TC 84A-5200 and TC 84A-5201

Ansell Healthcare Products LLC
1635 Industrial Road, Dothan, AL 36303
USA

1 800 952-9916 (USA)
1 800 363-8340 (CAN)
ansellhealthcare.com

NIOSH

APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS				
TC-	PROTECTION[1]	RESPIRATOR	RESPIRATOR	CAUTIONS AND LIMITATIONS[2]
		112410	112411	
84A-5200	N95	X		ABCJMNOPS
84A-5201	N95		X	ABCJMNOPS

1. Protection

N95 - Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply.

2. Cautions and Limitations

A - Not for use in atmospheres containing less than 19.5 percent oxygen.
B - Not for use in atmospheres immediately dangerous to life or health.
C - Do not exceed maximum use concentrations established by regulatory standards.
J - Failure to properly use and maintain this product could result in injury or death.
M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
P - NIOSH does not evaluate respirators for use as surgical masks.
S - Special or critical User's Instructions and/or specific use limitations may apply. Refer to User's Instructions before donning.

Use Information

1. Failure to follow all instructions and limitations can seriously reduce the effectiveness of this respirator and could lead to illness, injury or death.
2. Before occupational use, the wearer must be trained by the employer in the correct use of the respirator in accordance with applicable safety and health standards.
3. OSHA standards including 29CFR1910.134(e) (5) and CSA standard Z94.4-93 require that the wearer be fit-tested either qualitatively or quantitatively.
4. Discard the respirator and replace with a new one if:
   a. excessive clogging of the respirator causes breathing difficulty
   b. the respirator becomes damaged.
5. Discard the respirator and replace with a new one after every use.
6. Leave the contaminated area if dizziness, irritation or other distress occurs.

Use Limitations

1. Do not use the respirator or enter or stay in a contaminated area under the following circumstances:
   a. atmosphere contains less than 19.5% oxygen
   b. if you smell or taste a contaminant
   c. for protection against gases or vapors
   d. contaminants or their concentrations are unknown or immediately dangerous to life or health
   e. concentrations of contaminants exceed maximum use concentrations in applicable OSHA standards or applicable government regulations or 10 times the PEL (Permissible Exposure Limit), whichever is lower
   f. for sandblasting, paint-spray operations, asbestos exposure.
2. Do not alter, abuse or misuse the respirator.
3. Do not use the respirator with obstructive facial hair such as beards or with other conditions that may prevent a good seal between the face and the seating surface of the respirator.

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