May 16, 2023  
To: Indiana Hospital Association

In the last 30 days, 73 NIOSH approved respirators have been voluntarily rescinded. The manufactures include Honeywell, O&M Halyard, and E.D. Bullard Company. The following pages outline the specific models that no longer have NIOSH approval. Also included is information on Indiana Face Mask’s Surgical N95 that is still approved. Two fit test reports are also included to show a passing score for the clinically equivalent SA105 Surgical N95, and the 3M Aurora respirator.

Indiana Face Mask (IFM) strives on product performance and quality and has a continued commitment to the Indiana Hospital Association. IFM is willing to provide fit testing at no cost to the IHA Members who are willing to try IFM’s SA105 Surgical N95 respirator.

The current cost for the SA105 for all IHA members remains at $0.60 each / $72 per case of 120.

Please contact Adam Albrecht with inquiries on Fit Testing, Samples, Inventory, other USA made PPE, etc.

Adam Albrecht – Adam@ifmasks.com / 219-866-7735

Thank you for your time!

Adam Albrecht
Effective Immediately: Voluntary Rescission of certain Honeywell International Inc. Approvals

The National Institute for Occupational Safety and Health (NIOSH) has honored a request by Honeywell International Inc. to voluntarily rescind certain NIOSH respirator approvals issued to Honeywell International Inc.

As of April 14, 2023, any respirator marked with a NIOSH approval label with the below approval numbers are no longer NIOSH approved. The NIOSH Certified Equipment List no longer includes these approval numbers:

<table>
<thead>
<tr>
<th>84A-7483</th>
<th>84A-7469</th>
<th>84A-7476</th>
<th>84A-7490</th>
<th>84A-7497</th>
</tr>
</thead>
<tbody>
<tr>
<td>84A-7484</td>
<td>84A-7470</td>
<td>84A-7477</td>
<td>84A-7491</td>
<td>84A-7498</td>
</tr>
<tr>
<td>84A-7485</td>
<td>84A-7471</td>
<td>84A-7478</td>
<td>84A-7492</td>
<td>84A-7499</td>
</tr>
<tr>
<td>84A-7486</td>
<td>84A-7472</td>
<td>84A-7479</td>
<td>84A-7493</td>
<td>84A-7500</td>
</tr>
<tr>
<td>84A-7487</td>
<td>84A-7473</td>
<td>84A-7480</td>
<td>84A-7494</td>
<td>84A-7501</td>
</tr>
<tr>
<td>84A-7488</td>
<td>84A-7474</td>
<td>84A-7481</td>
<td>84A-7495</td>
<td>84A-7502</td>
</tr>
<tr>
<td>84A-7489</td>
<td>84A-7475</td>
<td>84A-7482</td>
<td>84A-7496</td>
<td>84A-7503</td>
</tr>
</tbody>
</table>

Due to the voluntary rescission of this NIOSH approval, respirators bearing these NIOSH approval numbers may no longer be used, manufactured, assembled, sold, or distributed.

Please reach out to Honeywell International Inc. for additional details related to their decision to voluntarily rescind the approvals issued to Honeywell International Inc. identified in this notice. The Certified Equipment List can be used to locate other NIOSH Approved® respirators.

NIOSH Approved® is a certification mark of the U.S. Department of Health and Human Services (HHS) registered in the United States and several international jurisdictions.
Effective Immediately: Voluntary Rescission of 24 E.D. Bullard Company Respirator Approvals

The National Institute for Occupational Safety and Health (NIOSH) has honored a request by E.D. Bullard Company to voluntarily rescind 24 NIOSH respirator approvals issued to E.D. Bullard Company.

As of April 21, 2023, any respirator marked with a NIOSH approval label with the below approval numbers are no longer NIOSH approved. The NIOSH Certified Equipment List no longer includes these approval numbers:

<table>
<thead>
<tr>
<th>19C-0540</th>
<th>19C-0549</th>
<th>19C-0559</th>
<th>19C-0567</th>
</tr>
</thead>
<tbody>
<tr>
<td>19C-0541</td>
<td>19C-0550</td>
<td>19C-0560</td>
<td>19C-0568</td>
</tr>
<tr>
<td>19C-0542</td>
<td>19C-0553</td>
<td>19C-0561</td>
<td>19C-0571</td>
</tr>
<tr>
<td>19C-0543</td>
<td>19C-0554</td>
<td>19C-0562</td>
<td>19C-0572</td>
</tr>
<tr>
<td>19C-0547</td>
<td>19C-0555</td>
<td>19C-0565</td>
<td>19C-0573</td>
</tr>
<tr>
<td>19C-0548</td>
<td>19C-0556</td>
<td>19C-0566</td>
<td>19C-0574</td>
</tr>
</tbody>
</table>

Due to the voluntary rescission of this NIOSH approval, respirators bearing these NIOSH approval numbers may no longer be used, manufactured, assembled, sold, or distributed.

Please reach out to E.D. Bullard Company for additional details related to their decision to voluntarily rescind the approvals issued to E.D. Bullard Company identified in this notice. The Certified Equipment List can be used to locate other NIOSH Approved® respirators.
Recommendations for Consumers, Healthcare Providers and Facilities Regarding Certain Surgical N95 Respirators by O&M Halyard

Dear HALYARD® customer,

At O&M Halyard, clinician and patient safety is our highest priority; therefore, we are notifying our customers of the following information.

We have been advised of NIOSH laboratory test results from one lot each of models 46727 and 46827 showing that O&M Halyard surgical N95 respirators do not meet fluid resistance performance expectations. The lot from model 46727 passed NIOSH filtration efficiency testing, however, the lot from model 46827 did not. The implied result is that these products may not provide expected protection to the wearer.

Effective April 12, O&M Halyard implemented a voluntary stop sale and delivery of the following N95 models.

Table 1: Surgical N95 Models Under a Voluntary Stop Sale and Delivery

<table>
<thead>
<tr>
<th>Model Name</th>
<th>Model Number</th>
<th>NIOSH Approval # TC -</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLUIDSHIELD® 3 N95 Particulate Filter Respirator and Surgical Mask, Orange, with SO SOFT* Lining, Regular Size</td>
<td>46727</td>
<td>84A-7521</td>
</tr>
<tr>
<td>FLUIDSHIELD® 3 N95 Particulate Filter Respirator and Surgical Mask, Orange, with SO SOFT* Lining, Small Size</td>
<td>46827</td>
<td>84A-7518</td>
</tr>
<tr>
<td>FLUIDSHIELD® 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining, Orange, Regular Size</td>
<td>46767</td>
<td>84A-7523</td>
</tr>
<tr>
<td>FLUIDSHIELD® 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining, Orange, Small Size</td>
<td>46867</td>
<td>84A-7520</td>
</tr>
<tr>
<td>FLUIDSHIELD® 3 N95 Particulate Filter Respirator and Surgical Mask, Orange, with SO SOFT* Lining, Regular Size</td>
<td>76727</td>
<td>84A-7521</td>
</tr>
<tr>
<td>FLUIDSHIELD® 3 N95 Particulate Filter Respirator and Surgical Mask, Orange, with SO SOFT* Lining, Small Size</td>
<td>76827</td>
<td>84A-7518</td>
</tr>
<tr>
<td>FLUIDSHIELD® 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining, Orange, Regular Size</td>
<td>76767</td>
<td>84A-7523</td>
</tr>
<tr>
<td>FLUIDSHIELD® 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining, Orange, Small Size</td>
<td>76867</td>
<td>84A-7520</td>
</tr>
</tbody>
</table>

All lots from those models listed in Table 1 should not be used when fluid resistance is required. O&M will update our notification upon completion of the fluid resistance investigation. While the investigation is ongoing, if fluid resistance is required while wearing these respirators, consider the additional use of a face shield.

O&M Halyard is conducting a thorough investigation, performing product retesting, and working closely with government agencies. To date, our investigation into particulate filtration has found that certain lots from model 46827 may have been tested using nonconforming equipment, which could have caused lots to be released based on inaccurate particulate filtration test results. We list the potentially affected lots for particulate filtration issues in the table below and will update our notification upon completion of the investigation.

Table 2: Potentially affected lots of model 46827 for particulate filtration concerns. These lots should not be used when respiratory protection or fluid resistance protection is required.

<table>
<thead>
<tr>
<th>Model</th>
<th>Lot Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>46827</td>
<td>AM2164811</td>
</tr>
<tr>
<td></td>
<td>AM2166811</td>
</tr>
</tbody>
</table>

The lot number can be found on the label of the product codes depicted below:
KEY FEATURES
• Meets NIOSH Title 42, Code of Federal Regulations, Part 84 (42 CFR 84).
• Approved for use in Healthcare
• Adjustable nose clip with comfort soft nose foam for a secure seal.
• Latex free: YES
• Model: Flat Fold
• Filtration Efficiency: >97%
• Exceeds Particulate Filtration Efficiency (PFE) per ASTM F2299 Standard.
• Exceeds Breathability per Test MIL-M-36954 C: ΔP Standard.
• Individually Wrapped for best work place practices

MATERIAL COMPOSITION
• Outer Layer: Polypropylene spunbond
• Filter: Melt-blown non-woven electro-statically charged 3 layers
• Inner Layer: Polypropylene spunbond
• Nose Clip: Polyethylene coated double wire
• Head Strap: Elastic spandex

FSSC, LLC dba Indiana Face Mask | 3300 West Clark Street, Rensselaer, IN 47978 | ContactUs@ifMasks.com
This literature and information can not be modified or duplicated without manufacturers written consent
FIT TEST REPORT

Date: May 10, 2023
Facility: IFM Laboratory 1
Standard: ASTM F3407
Equipment: AccuFit 9000
- AccuFit 9000 Pro - Condensation Nuclei Counter with particle classifier technology
- Isolation Test Chamber – ASTM F3407
- NaCl Aerosol Particle Generator
- NaCl – Fisher Bio Reagent # BP3581
- Digital Humidity and Thermometer – MFR P/N 00325A1
- Mirror
- Digital Calipers
- Outside Calipers
- ToxiRAE Pro Oxygen O2 Detector

Test Article: SA105 / 3M Aura 9205+
Article ID: SA105 / 3M Aura
STP: SOP-053

SUMMARY

Test subjects are selected using the NIOSH Bivariate Test Panel representing a range of face sizes. Each subject enters the test chamber with the selected half-face respirator with a probe connected to the AccuFit 9000. An NaCl aerosol generator fills the test chamber. The aerosol concentration shall be well mixed (that is, uniformly distributed) throughout the chamber (+/- 10 %) where the test subject(s) will be performing the test. The concentration shall be stable (that is, +/- 10 % of the initial concentration of between 2000 and 800 particles/cm3) for the duration of the test. The particles in the chamber should between 0.02 μm and 1 μm with a geometric standard deviation ≤2.2. The airflow through the test chamber shall be sufficient to maintain the temperature between 21 °C and 24 °C, the relative humidity below 40 % to prevent agglomeration of the sodium chloride test agent, and the oxygen level above 19.5 %. The test subject will perform the required RFC exercises for the required times. The subject must reach a RFC result of ≥ 100 to pass and be considered a proper fit.
Test Subject: Adam Albrecht
ID Number: 01
Gender: Male
Face Size W x L (mm) : 134 x 119
Cell Number: 7
Temperature: 72F
Humidity %: 38

<table>
<thead>
<tr>
<th>Aerosol Concentration (Particles/Cm³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning</td>
</tr>
<tr>
<td>5210</td>
</tr>
</tbody>
</table>

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

Outside Calipers, Digital Calipers
Used for measuring Bizygomatic Breadth & Menton-Sellion Length
FIT TEST REPORT
May 10, 2023

EMP. ID: 02
LAST NAME: Albrecht
FIRST NAME: Adam
COMPANY: IFM

Test Date: May 10, 2023 13:12
DUE DATE: May 10, 2024

RESPIRATOR: IFM SA105 Surgical N95 [100]
MANUFACTURER: IFM
MODEL: SA105
MASK STYLE: Surgical N95
MASK SIZE: One Size Fits All

EXERCISE | DURATION | FIT FACTOR | PASS
---|---|---|---
Normal Breathing | 60 | 234 | Y
Deep Breathing | 60 | 139 | Y
Turn Head Side to Side | 60 | 460 | Y
Move Head Up and Down | 60 | 139 | Y
Speak Aloud / Read Passage | 60 | 100 | Y
Grimace | 15 | Excl. | 
Bending Over | 60 | 130 | Y
Normal Breathing | 60 | 249 | 

OVERALL FF: 165

FIT TEST OPERATOR: Clay Geyer
DATE: May 10, 2023

NAME: Adam Albrecht
DATE: May 10, 2023

FIT TEST REPORT
May 10, 2023

EMP. ID: 02
LAST NAME: Albrecht
FIRST NAME: Adam
COMPANY: IFM

Test Date: May 10, 2023 13:12
DUE DATE: May 10, 2024

RESPIRATOR: IFM SA105 Surgical N95 [100]
MANUFACTURER: IFM
MODEL: SA105
MASK STYLE: Surgical N95
MASK SIZE: One Size Fits All

EXERCISE | DURATION | FIT FACTOR | PASS
---|---|---|---
Normal Breathing | 60 | 234 | Y
Deep Breathing | 60 | 139 | Y
Turn Head Side to Side | 60 | 460 | Y
Move Head Up and Down | 60 | 139 | Y
Speak Aloud / Read Passage | 60 | 100 | Y
Grimace | 15 | Excl. | 
Bending Over | 60 | 130 | Y
Normal Breathing | 60 | 249 | 

OVERALL FF: 165

FIT TEST OPERATOR: Clay Geyer
DATE: May 10, 2023

NAME: Adam Albrecht
DATE: May 10, 2023

Respirator Fit Test Card
Name: Adam Albrecht  Test Date: May 10, 2023
ID: 02  Next Test Date: May 10, 2024

Respirator
Mfg: IFM
Model: SA105
Style: Surgical N95
Size: One Size Fits All

Results
Overall FF: 165
Pass Level: 100
Operator: Clayton Geyer
Protocol: ASTM F3407-20
Fit Test Method: QNFT using AccuFIT
### FIT TEST REPORT
May 10, 2023

**EMP. ID**: 02  
**LAST NAME**: Albrecht  
**FIRST NAME**: Adam  
**COMPANY**: IFM

<table>
<thead>
<tr>
<th>Test Date</th>
<th>14:09</th>
<th>AccuFIT9000 S/N 686183</th>
</tr>
</thead>
<tbody>
<tr>
<td>DUE DATE</td>
<td>May 10, 2024</td>
<td></td>
</tr>
<tr>
<td>RESPIRATOR</td>
<td>3M Aura 9205+ N95 [100]</td>
<td></td>
</tr>
<tr>
<td>MANUFACTURER</td>
<td>3M</td>
<td></td>
</tr>
<tr>
<td>MODEL</td>
<td>Aura 9205+</td>
<td></td>
</tr>
<tr>
<td>MASK STYLE</td>
<td>N95</td>
<td></td>
</tr>
<tr>
<td>MASK SIZE</td>
<td>One Size Fits All</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EXERCISE</th>
<th>DURATION</th>
<th>FIT FACTOR</th>
<th>PASS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Breathing</td>
<td>60</td>
<td>391</td>
<td>Y</td>
</tr>
<tr>
<td>Deep Breathing</td>
<td>60</td>
<td>573</td>
<td>Y</td>
</tr>
<tr>
<td>Turn Head Side to Side</td>
<td>60</td>
<td>155</td>
<td>Y</td>
</tr>
<tr>
<td>Move Head Up and Down</td>
<td>60</td>
<td>155</td>
<td>Y</td>
</tr>
<tr>
<td>Speak Aloud / Read Passage</td>
<td>60</td>
<td>185</td>
<td>Y</td>
</tr>
<tr>
<td>Grimace</td>
<td>15</td>
<td>EXC.</td>
<td></td>
</tr>
<tr>
<td>Bending Over</td>
<td>60</td>
<td>38</td>
<td>N</td>
</tr>
<tr>
<td>Normal Breathing</td>
<td>60</td>
<td>53</td>
<td>N</td>
</tr>
</tbody>
</table>

**OVERALL FF**: 102  
**FIT TEST OPERATOR**: Clayton Geyer  
**DATE**: May 10, 2023

**NAME**: Adam Albrecht  
**DATE**: May 10, 2023

**Misc**: ADMIN

---

**Respirator Fit Test Card**

- **Name**: Adam Albrecht  
- **ID**: 02  
- **Test Date**: May 10, 2023  
- **Next Test Date**: May 10, 2024

**Respirator**

- Mfg: 3M  
- Model: Aura 9205+  
- Style: N95  
- Size: One Size Fits All

**Results**

- Overall FF: 103  
- FF Pass Level: 100  
- Pass: Y  
- Operator: Clayton Geyer  
- Protocol: ASTM F3407-20  
- Fit Test Method: QNFT using AccuFIT