FSSC, LLC dba Indiana Face Mask
3300 West Clark Street
Rensselaer, IN 47978

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In the last 30 days, 73 NIOSH approved respirators have been voluntarily rescinded.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 inquires 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:**

84A-7483	**84A-7469**	**84A-7476**	**84A-7490**	**84A-7497**
84A-7484	**84A-7470**	**84A-7477**	**84A-7491**	**84A-7498**
84A-7485	**84A-7471**	**84A-7478**	**84A-7492**	**84A-7499**
84A-7486	**84A-7472**	**84A-7479**	**84A-7493**	**84A-7500**
84A-7487	**84A-7473**	**84A-7480**	**84A-7494**	**84A-7501**
84A-7488	**84A-7474**	**84A-7481**	**84A-7495**	**84A-7502**
84A-7489	**84A-7475**	**84A-7482**	**84A-7496**	**84A-7503**

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.

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:**

19C-0540	**19C-0549**	**19C-0559**	**19C-0567**
19C-0541	**19C-0550**	**19C-0560**	**19C-0568**
19C-0542	**19C-0553**	**19C-0561**	**19C-0571**
19C-0543	**19C-0554**	**19C-0562**	**19C-0572**
19C-0547	**19C-0555**	**19C-0565**	**19C-0573**
19C-0548	**19C-0556**	**19C-0566**	**19C-0574**

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.

Product Communications

View the latest product communications for our portfolio

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

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

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.

Model	Lot Numbers
46827	AM2164811
	AM2166811

The lot number can be found on the label of the product codes depicted below:

INDIANA FACE MASK

SURGICAL N95 SA105
PARTICULATE RESPIRATOR

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

MADE IN USA

National Institute for Occupational Safety and Health NIOSH®

SPECIFICATIONS

Part Number	SA105
TC Number	**TC-84A-9440**
Location	Manufactured in Indiana, USA
Description	Surgical N95 Particulate Respirator

PACKAGING

Box Quantity	20 Individual Respirators
Master Pack	6 Boxes (120 Respirator) 17 L x 12 W x 11 H * 8 Lbs
Pallet Quantity	35 Master Packs (**4,200** Respirators)
Pallet Dimension	43x43x59

FSSC, LLC dba Indiana Face Mask | 3300 West Clark Street, Rensselaer, IN 47978 | ContactUs@IFMasks.com

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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.

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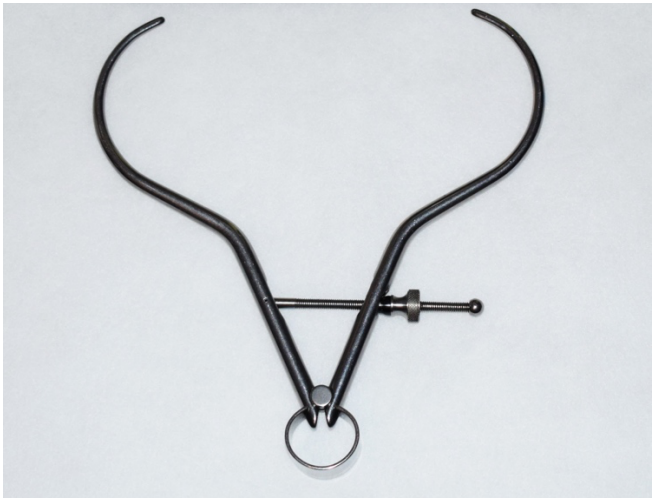
Test Subject: Adam Albrecht
ID Number: 01
Gender: Male
Face Size W x L (mm) : 134 x 119
Cell Number: 7
Temperature: 72F
Humidity %: 38

Aerosol Concentration (Particles/Cm^3)	
Beginning	End
5210	5480

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



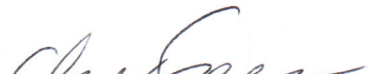
FIT TEST REPORT

May10,2023

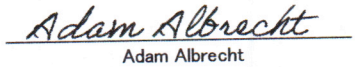
EMP. ID	02
LAST NAME	Albrecht
FIRST NAME	Adam
COMPANY	IFM

Test Date	May10,2023 13:12	AccuFIT9000 S/N	686183
DUE DATE	May10,2024		
RESPIRATOR	IFM SA105 Surgical N95 [100]	PROTOCOL	ASTM F3407-20
MANUFACTURER	IFM	PASS LEVEL	100
MODEL	SA105		
MASK STYLE	Surgical N95	APPROVAL	
MASK SIZE	One Size Fits All		

EXERCISE	DURATION	FIT FACTOR	PASS
Normal Breating	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	Y
OVERALL FF		165	Y

FIT TEST OPERATOR  DATE May 10, 2023

Clayton Geyer

NAME  DATE May 10, 2023

Adam Albrecht

Misc: ADMIN

Respirator Fit Test Card

Name:Adam Albrecht
ID:02

Test Date:May10,2023
Next Test Date:May10,2024

Respirator

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

Results

Overall FF:165
FF Pass Level:100
Pass:Y
Operator:Clayton Geyer

Protocol:ASTM F3407-20

Fit Test Method:QNFT using AccuFIT

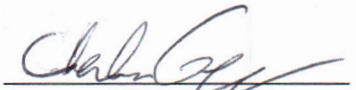
FIT TEST REPORT

May10,2023

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

Test Date	May10,2023 14:09	AccuFIT9000 S/N	686183
DUE DATE	May10,2024		
RESPIRATOR	3M Aura 9205+ N95 [100]		
		PROTOCOL	ASTM F3407-20
MANUFACTURER	3M	PASS LEVEL	100
MODEL	Aura 9205+		
MASK STYLE	N95	APPROVAL	
MASK SIZE	One Size Fits All		

EXERCISE	DURATION	FIT FACTOR	PASS
Normal Breating	60	391	Y
Deep Breathing	60	573	Y
Turn Head Side to Side	60	155	Y
Move Head Up and Down	60	156	Y
Speak Aloud / Read Passage	60	185	Y
Grimace	15	Excl.	
Bending Over	60	38	N
Normal Breathing	60	53	N
OVERALL FF		103	Y

FIT TEST OPERATOR  DATE May 10, 2023

Clayton Geyer

NAME Adam Albrecht DATE May 10, 2023

Adam Albrecht

Misc: ADMIN

Respirator Fit Test Card

Name:Adam Albrecht Test Date:May10,2023

ID:02 Next Test Date:May10,2024

Respirator	Results
Mfg:3M	Overall FF:103
Model:Aura 9205+	FF Pass Level:100
Style:N95	Pass:Y
Size:One Size Fits All	Operator:Clayton Geyer

Protocol:ASTM F3407-20

Fit Test Method:QNFT using AccuFIT