WISCONSIN DEPARTMENT of HEALTH SERVICES

INTERIM Guidance Document for Respirator Use

The Occupational Safety and Health Administration (OSHA) has developed a guidance document for healthcare workers and employers as well as an occupational exposure risk pyramid. Utilizing these documents as well as materials from the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) we have developed the following reference information regarding filtering face piece respirators (FFR).

This document is intended for those who are currently using UVC or vaporous hydrogen peroxide (VHP) for decontamination, or time for inactivation of FFRs. It should be noted that all respirator use for the purpose of employee protection must be performed through a respiratory protection program as required by OSHA. More information can be found at this LINK.

The guidance in this document should viewed as a work in progress. This guidance document will be updated periodically as new scientific literature and empirical data become available.

The chart presented in this document will hopefully provide additional guidance and answers regarding use of respirators and personnel safe practices. The information provided here was obtained by researching multiple sources as well as using scientific literature and empirical data, where available. It is important to note that due to the ever changing dynamics of COVID-19 and that employer/employee duties can change rapidly during this pandemic, individuals may shift from one exposure risk level to another requiring them to follow different protocols and PPE usage as needed. If you have additional questions please refer to the attached links for further information.

Individuals in Very High Risk or High Risk Categories (should follow FDA EUA guidelines regarding the use of KN95 and N95 respirators at all times).

Very High Risk (Performing aerosol generating procedures)

- Physicians, physician assistants
- Dentists, dental hygienists, dental assistants
- Nurses
- Paramedics
- Emergency medical technicians
- Healthcare or lab personnel collecting and handling suspected or known COVID-19 specimens
- Morgue workers

High Risk (jobs with high exposure to known or suspected sources of SARS-CoV-2)

- Healthcare delivery and support staff
- Medical transport workers
- Research or production lab workers
- Environmental services (e.g., Janitors) in high exposure areas

Individuals in the Medium to Lower Risk Category (may follow evidence-based or scientific-based protocols for use of KN95 and N95 respirators):

- Ancillary healthcare workers (admission and administrative staff)
- Emergency Response (law enforcement officers, firefighters, etc.)
- Transit workers
- Solid waste and wastewater management
- Research or production lab workers
- Environmental (e.g., janitorial) services
- Correctional facility operations

For individuals in the medium and lower risk group a procedural or facemask may provide adequate protection and thereby conserve the supply of respirators. As noted previously, risk categories may change exposing workers to elevated risks and thereby requiring a change in PPE usage. In these scenarios the individual(s) should follow the FDA EUA and NIOSH standard for PPE usage.

Please note that these lists are to serve as guidance and are by no means all inclusive. If questions or concerns develop you should consult the CDC, FDA, or OSHA for additional information on conservation and proper usage (including donning and doffing) of PPE.

An additional technique for preserving the viability of respirators is to use a procedural mask over the respirator and in areas of high aerosol generating procedures use of a face shield and eye protection with non-perforated side shields is recommended.

CDC Guidance for Respirator Re-Use[1, 2]

The CDC describes different strategies that may be employed depending on the available respirator supply. These strategies are classified as:

Conventional Capacity (incorporated into everyday practices)

This set of measures, consists of engineering, administrative, and PPE control plans in healthcare settings. Examples include:

- Training on appropriate indicators for respirator use
- Just-in-time fit testing
- Qualitative fit testing
- Source control
- Use of acceptable alternatives such as particulate filters rated N, R, or P, and that have efficiency ratings of 95, 99, or 100
- Full range of filtration rating indictors can be found at this LINK.

Contingency Capacity (during **expected** shortages)

Consists of measures that may change daily standard practices but may not have any significant impact on the care delivered to the patient or the safety of first responders. Examples include:

- Respirator use beyond shelf life
- Extended use of N95 respirators

Crisis Capacity (during **known** shortages):

These are strategies that are not in conjunction with U.S. standards of care. Examples include:

- Limited re-use of respirators
- Prioritizing respirator use by activity type
- Use beyond shelf life
- Allow for decontamination of respirators

Moving to crisis strategies should only be done after implementing all conventional and contingency strategies. Facilities should understand their respirator utilization rate, attempt to obtain additional supplies, and ensure personnel have been provided all required education and training. Crisis strategies involve non-routine operations that don't follow the normal standards of care. This includes the potential of decontamination and reuse of N95 respirators in order to provide the best available protection to workers under situations of scarcity. Additional strategies can be found at this LINK.

The CDC has provided strategies for optimizing the supply of N95 respirators. These strategies have been further researched and approved by the authors' of this document. Strategies include:

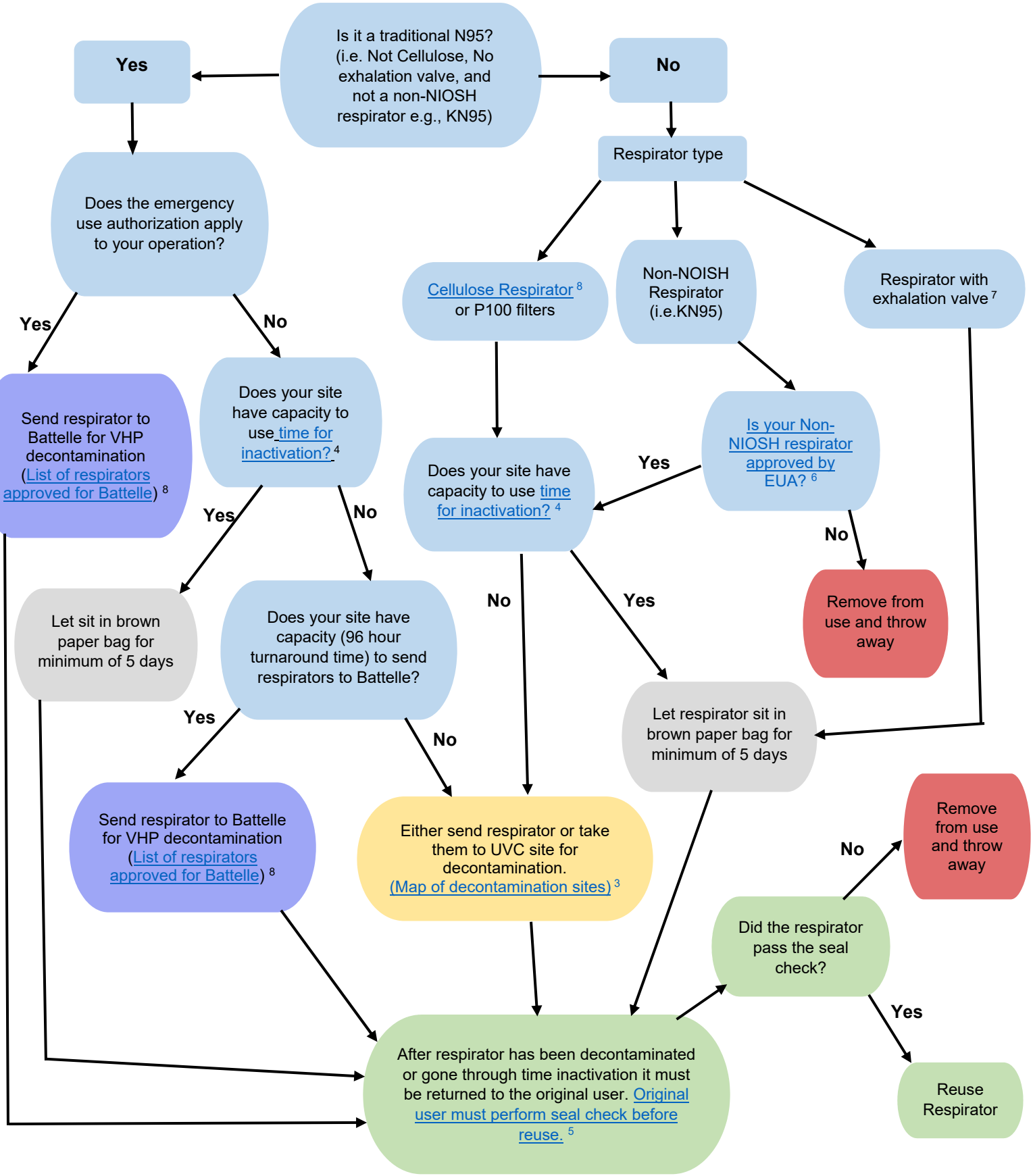
1) Time for inactivation (COVID-19 specific)
    a. Is the easiest option available (just hold onto respirator and let it sit for 5 days).
    b. To use time for inactivation keep respirator in breathable paper bag.
    c. This is the only available option for the decontamination of N95 respirators with exhalation valves.

2) Vaporous hydrogen peroxide (VHP)
    a. There is a large VHP decontamination site in Madison, WI.
    b. Respirators sent here must meet specific guidance provided in this document.
    c. This systems main users will be those who fall under the Emergency Use Authorization (primarily healthcare).

3) Ultraviolet Germicidal Irradiation (UVGI or UVC)
    a. Should be used primarily by first responders (Police, EMS, and Fire).
    b. There are multiple UVC decontamination sites across Wisconsin. A map LINK has been provided.[3]

Organizations that use one of the strategies listed above must have a user preform a seal check before reuse. If a respirator does not pass a seal check it should be thrown away. Decontamination of respirators should be kept to a minimum to avoid degradation.

Where to Send Respirator for Decontamination



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Links in Document

[1] Strategies for optimizing the supply of N95 Respirators:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html

[2] Respirator Trusted Source Information
https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource1quest2.html

[3] Map of decontamination sites:
https://wem.maps.arcgis.com/apps/View/index.html?appid=0edf7bbed498430f86b46d3d06b468 a2

[4] Decontamination and Reuse of respirators:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html

[5] How to perform a seal check on a respirator:

https://www.youtube.com/watch?v=pGXiUyAoEd8

[6] Respirator models no longer authorized:

https://www.fda.gov/media/137928/download

[7] Exhalation Valve Language:

https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

An N95 respirator with an exhalation valve does provide the same level of protection to the wearer as one that does not have a valve. The presence of an exhalation valve reduces exhalation resistance, which makes it easier to breathe (exhale). Some users feel that a respirator with an exhalation valve keeps the face cooler and reduces moisture build up inside the facepiece. However, respirators with exhalation valves should not be used in situations where a sterile field must be maintained (e.g., during an invasive procedure in an operating or procedure room) because the exhalation valve allows unfiltered exhaled air to escape into the sterile field.

An N95 with an exhalation valve should also only use time for inactivation. This is the preferred method because the exhalation valve allows for shadowing on the mask which would not allow for UVC to decontaminate the whole surface area. Furthermore, companies like Battelle are no longer allowing respirators with exhalation valves to be decontaminated using vaporous hydrogen peroxide.

[8] Guide for Identifying FDA EUA Authorized N95 Respirators for Battelle CCDS™ Processing
Guide for Identifying FDA EUA Authorized N95 Respirators for Battelle CCDS™ processing – updated June 10, 2020

Additional Helpful Links

1. OSHA respiratory protection standard:
   https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134

2. How to properly put on and take off a disposable respirator:
   https://www.cdc.gov/niosh/docs/2010-133/pdfs/2010-133.pdf?id=10.26616/NIOSHPUB2010133
   or
   https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/fs-respirator-on-off.pdf

3. Proper use of respirators for healthcare workers and first responders:
   https://aiha-assets.sfo2.digitaloceanspaces.com/AIHA/resources/Public-Resources/RespiratorInfographic.pdf

4. The Emergency use authorizations available for Non-NIOSH respirators:
   https://www.fda.gov/media/136403/download

5. Counterfeit Respirators/ Misrepresentation of NIOSH-Approval
   https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

6. The NPPTL Respirator Assessments to support the COVID-19 Response
   The National Personal Protective Technology Laboratory (NPPTL) preformed assessments of filter efficiency for those respirators represented as certified by an international certification authority other than NIOSH, to support respiratory protection effects in the US. These studies looked to examine overall performance. (International Assessment Results – Not NIOSH- Approved):
   https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html

7. Certified Equipment List Search for respirators:
   This link can be used to determine what is currently approved for use.
   https://www2a.cdc.gov/drds/cel/cel_form_code.asp

8. PPE Decontamination UVC Process training videos:
   The below link features videos which are to provide general information and refresher training for Wisconsin Emergency Operation Sites which are using UVC radiation for decontamination. There is also additional information on the alternative methods of decontamination such as vaporous hydrogen peroxide and time for inactivation. http://www.slh.wisc.edu/ppe-decon-uv-c/

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[6] Guide for Identifying FDA EUA Authorized N95 Respirators for Battelle CCDS™ Processing – *updated June 10, 2020*

Battelle, using the Battelle CCDS Critical Care Decontamination System™, has been authorized under the updated FDA EUA[1] to decontaminate N95 or N95 equivalent filtering face piece respirators (FFR or respirators) that do not contain cellulose and do not have exhalation valves. Respirators that contain cellulose-based materials or have an exhalation valve are excluded from the Battelle CCDS™ EUA and cannot be processed using Battelle CCDS™.

The FDA EUA does not authorize decontamination of KN95 or other non-NIOSH-approved FFRs manufactured in China**.** In addition**,** Battelle does not process FFR previously decontaminated using alternate systems or processes (e.g., UV irradiation).

Battelle is providing the following information to assist hospitals with identifying compatible N95 respirators. It is the responsibility of the organization to ensure only compatible FFR are transported to Battelle for decontamination. **Compatible FFR include NIOSH-approved N95 and non-NIOSH approved respirators listed in Exhibit 1[2] that:**

- **do not have exhalation valves,**
- **do not contain cellulose-based materials, and**
- **do not contain activated carbon.**

NIOSH Respirators: A list of NIOSH-approved N95 Particulate FFRs can be found at this CDC website.[3] Only approved models that do not contain cellulose or activated carbon and do not have exhalation valves should be submitted to the Battelle CCDS™ program for decontamination.

Non-NIOSH Respirators: Respirators must be certified by NIOSH or be listed in the FDA EUA update on June 6, 2020[4] approving the use of certain imported non-NIOSH disposable FFRs. Exhibit 1 of the EUA provides a detailed list of approved makes and models.

Expired N95 Respirators: The FDA has also approved the use of certain makes and model of N95s and FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf life, are not damaged, and have been held in accordance with manufacturers' storage conditions in strategic stockpiles. The criteria under which these FFRs can be used can be found in the EUA.[4] Review this information to ensure what types of FFRs are authorized. Expired, EUA authorized, N95s that do not contain cellulose or activated carbon and do not have exhalation valves are able to be decontaminated with Battelle CCDS™.

[a] This model is equipped with an exhalation valve; respirators that have an exhalation valve are no longer authorized for decontamination, according to the revised FDA EUA released June 6, 2020 https://www.fda.gov/media/136529/download.

Below are tables that contain common N95 respirator manufacturers and product models. Included is information if the model is known to contain cellulose or activated carbon and if it is able to be processed using the Battelle CCDS™ process. *This list is not exhaustive. If you have questions about a different respirator model, please contact the manufacturer or supplier directly*.

- **3M** - (800) 243-4630 • **Halyard** – (844) 425-9273 • **Moldex** – (800) 421-0668 Ext 512
- **Cardinal Health** – (800) 964-5227 • **Honeywell** – (877) 841-2840 • **Prestige Ameritech** – (817) 427• **Dräger** – (800) 437-2437 • **Kimberly-Clark** – (888) 346-4652 2700
- **Gerson** – (508) 947-4000 • **Medline** – (855) 294-9618

Select 3M N95 and FFR processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[5]	Battelle CCDS™ processable
3M	N95, Health Care Particulate Respirator and Surgical Mask **1860** and **1860S**	NO	YES
3M	N95, Aura Health Care Particulate Respirator and Surgical Mask **1870** and **1870+**	NO	YES
3M	N95, Particulate Respirator **8110S**	NO	YES
3M	P2, Particulate Respirator **8205**	NO	YES
3M	N95, Particulate Respirator **8210**	NO	YES
3M	N95, Particulate Respirator **8210Plus**	NO	YES
3M	N95, Particulate Respirator **8510**	NO	YES
3M	N95, Aura Particulate Respirator **9205+**	NO	YES
3M	N95, Aura Particulate Respirator **9210**, **9210+**	NO	YES
3M	FFP2, P2, Aura Particulate Respirator **9320+**	NO	YES
3M	N95, Particulate Respirator **9502+**	NO	YES
3M	N95, Vertical Flat Fold Respirator **9820**	NO	YES
3M	N95, VFlex Healthcare Particulate Respirator and Surgical Mask **1804** and **1804S**	YES	NO
3M	N95, VFlex Health Care Particulate Respirator and Surgical Mask **1805** and **1805S**	YES	NO
3M	N95, Particulate Respirator **8000**	YES	NO
3M	N95, Particulate Respirator **8200**	YES	NO
3M	N95, Particulate Respirator **8210V**	NO	NO[a]
3M	N95, Particulate Respirator **8211**	NO	NO[a]
3M	N95, Particulate Welding Respirator **8212**	YES	NO[a]
3M	N95, Particulate Respirator with Faceseal **8214**	YES	NO[a] (contains carbon)
3M	N95, Particulate Respirator **8511**	NO	NO[a]

[a] This model is equipped with an exhalation valve; respirators that have an exhalation valve are no longer authorized for decontamination, according to the revised FDA EUA released June 6, 2020 https://www.fda.gov/media/136529/download.

3M	N95, Particulate Respirator **8511P**	YES	NO[a]
3M	N95, Particulate Welding Respirator **8512**	YES	NO[a]
3M	N95, Particulate Respirator **8514**	YES	NO[a] (contains carbon)
3M	N95, Particulate Welding Respirator **8515**	NO	NO[a]
3M	N95, Particulate Respirator **8516**	NO	NO[a] (contains carbon)
3M	FFP2, Particulate Respirator **8822**	YES	NO[a]
3M	N95, **9010**, **9010CN**, and **9010MX**	YES	NO
3M	N95, Particulate Respirator **9010V**	YES	NO[a]
3M	N95, VFlex Particulate Respirator **9105**, **9105S**	YES	NO
3M	N95, Particulate Respirator Surgical Mask **9132**	YES	NO
3M	N95, Aura Particulate Respirator **9211**, **9211+**	NO	NO[a]
3M	FFP2, Aura Particulate Respirator **9322+**	NO	NO[a]

Select Cardinal Health N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[6]	Battelle CCDS™ Processable
Cardinal Health	N95, **USA-N95-S** and **USA-N95-R** Alternate labels: **Prestige Ameritech USA-N95-S** and **USA-N95-R**	NO	YES
Cardinal Health	N95, **N95A-S** and **N95A-ML** Alternate labels: **Makrite 9500-N95** and **9500-N95S**	NO	YES

Select Draeger N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[7]	Battelle CCDS™ Processable
Dräger	N95, X-plore **1750**	NO	YES
Dräger	N95, X-plore **1750 V**	NO	NO[a]
Dräger	N95, X-plore **1750 V Odor**	NO	NO (contains carbon)

Select Gerson N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[8]	Battelle CCDS™ Processable
Gerson	N95, **1730**	NO	YES
Gerson	N95, **2130**	YES	NO
Gerson	N95, **2140**	YES	NO[a]

Select Halyard N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[9,10]	Battelle CCDS™ Processable
Halyard	N95, **46727**	NO	YES
Halyard	N95, **46767**	NO	YES
Halyard	N95, **46827**	NO	YES

[a] This model is equipped with an exhalation valve; respirators that have an exhalation valve are no longer authorized for decontamination, according to the revised FDA EUA released June 6, 2020 https://www.fda.gov/media/136529/download.

Halyard	N95, **46867**	**NO**	**YES**
Halyard	N95, **62126**	**NO**	**YES**
Halyard	N95, **62355**	**NO**	**YES**

Select Honeywell N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[11]	Battelle CCDS™ Processable
Honeywell	N95, North SAF-T-FIT Plus **N1105**	**NO**	**YES**
Honeywell	N95, Sperian ONE-Fit **NBW95** Alternate label: **Willson NBW95**	**NO**	**YES**
Honeywell	N95, Sperian ONE-Fit **W1400**	**NO**	**YES**
Honeywell	N95, Sperian ONE-Fit **HC-NB295F**	**NO**	**YES**
Honeywell	N95, North SAF-T-FIT Plus **N1125**	**NO**	**NO**[a]
Honeywell	N95, Sperian ONE-Fit **NBW95V**	**NO**	**NO**[a]

Select Kimberly-Clark N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose	Battelle CCDS™ Processable
Kimberly-Clark	N95, **46727**	**NO**[10]	**YES**
Kimberly-Clark	N95, **46767**	**NO**[10]	**YES**
Kimberly-Clark	N95, **46827**	**NO**[10]	**YES**
Kimberly-Clark	N95, **46867**	**NO**[10]	**YES**
Kimberly-Clark	N95, **62126**	**NO**[10]	**YES**
Kimberly-Clark	N95, **62355**	**NO**[10]	**YES**
Kimberly-Clark	N95, **64230 and 64240** Alternate labels: **SureWerx KIM 64230** and **KIM 64240**, **Jackson Industrial 64230** and **64240**	**NO**[12,13]	**YES**

Select Makrite N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[14,15]	Battelle CCDS™ Processable
Makrite	N95, **9500-N95**, **9500-N95S**, **MK910-N95**, and **MK910-N95S**	**NO**	**YES**
Makrite	N95, **MKN95-910V** and **9500V-N95**	**NO**	**NO**[a]
Makrite	N95, **9500-N95OV** and **MK910-N95OV**	**NO**	**NO** **(contains carbon)**
Makrite	N95, **9500-N95VOV** and **MK910-N95VOV**	**NO**	**NO**[a] **(contains carbon)**

Select Medline N95 processability using Battelle CCDS™

[a] This model is equipped with an exhalation valve; respirators that have an exhalation valve are no longer authorized for decontamination, according to the revised FDA EUA released June 6, 2020 https://www.fda.gov/media/136529/download.

Manufacturer/ Supplier	Model	Known to contain cellulose[16]	Battelle CCDS™ Processable
Medline	N95, **NON24506A**	NO	YES
Medline	N95, **NON24507** and **NON24507A**	NO	YES
Medline	N95, **RP88020** and **RP88010** Alternate labels: **Prestige Ameritech**, **RP88020** and **RP88010**	NO	YES
Medline	N95, **NON24509**	NO	NO[a]
Medline	N95, **NON27501** Alternate labels: **Alpha ProTech 695** and **ProTech NON27501**	YES	NO

Select Moldex N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[17,18]	Battelle CCDS™ Processable
Moldex	N95, **1200N95, 1201N95,** and **1207N95**	NO	YES
Moldex	N95, **1510, 1511**, **1512**, **1513**, and **1517**	NO	YES
Moldex	N95 FastFit Flat Fold, **1712**	NO	YES
Moldex	N95 FastFit Flat Fold, **2112**	NO	YES
Moldex	N95, **2200N95**, **2201N95**, **2207N95,** and **2212N95** Alternate label: **ULINE S-15312**	NO	YES
Moldex	N95, **2600N95**, **2601N95**, and **2607N95**	NO	YES
Moldex	N95, **4200** and **4201** Alternate label: **ULINE S-19255**	NO	YES
Moldex	N95, **4600** and **4601**	NO	YES
Moldex	N95, **2300N95**, **2301N95**, and **2307N95** Alternate label: **ULINE S-15313**	NO	NO[a]
Moldex	N95, **2400N95** Alternate label: **ULINE S-19256**	NO	NO[a] (contains carbon)
Moldex	N95, **2500N95**	NO	NO[a] (contains carbon)
Moldex	N95, **2700N95**, **2701N95,** and **2707N95**	NO	NO[a]
Moldex	N95, **2800N95** and **2801N95**	NO	NO[a] (contains carbon)
Moldex	N95, **4800**	NO	NO (contains carbon)

Select Prestige Ameritech N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[19,16]	Battelle CCDS™ Processable
Prestige Ameritech	N95, **RP88020** and **RP88010** Alternate labels: **ProGear RP88020** and **Medline RP88020** and **RP88010**	NO	YES

[a] This model is equipped with an exhalation valve; respirators that have an exhalation valve are no longer authorized for decontamination, according to the revised FDA EUA released June 6, 2020 https://www.fda.gov/media/136529/download.

Prestige Ameritech	N95, **USA-N95-S** and **USA-N95-R**	**NO**	**YES**

Select San Huei N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose	Battelle CCDS™ Processable
San Huei	N95, **SH2550** Alternate labels: **Gateway Safety PeakFit 80101**	**NO**[20]	**YES**
San Huei	N95, **SH2950** Alternate labels: **Gateway Safety SaniFold 80201** and **Maytex 3380**	**NO**[20, 21]	**YES**
San Huei	N95, **SH9550** Alternate labels: **Maytex 3395** and **Uline S-9632**	**NO**[22,23,24]	**YES**
San Huei	N95, **SH2550V** Alternate labels: **Gateway Safety PeakFit 80102V** **Uline S-19253**	**NO**[20,25]	**NO**[a]
San Huei	N95, **SH2550CV** and **SH2950CV** Alternate Label: **Gateway Safety PeakFit 80104CV**	**NO**[20]	**NO**[a] **(contains carbon)**
San Huei	N95, **SH2950V** Alternate labels: **Gateway Safety SaniFold 80202V** and **Maytex 3380V**	**NO**[20,21]	**NO**[a]
San Huei	N95, **SH9550V** Alternate labels: **Maytex 3395V**	**NO**[22,23]	**NO**[a]

Select Suzhou Sanical Protective Product Manufacturing N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose	Battelle CCDS™ Processable
Suzhou Sanical	N95, Benehal **MS6115L**	**YES**[26,27]	**NO**
Suzhou Sanical	N95, Benehal **MS8225**	**YES**[28]	**NO**
Suzhou Sanical	N95, Benehal **MS8265** Alternate labels: **Direct Relief DRN95-1**	**NO**[30,31]	**NO**[a]

[a] This model is equipped with an exhalation valve; respirators that have an exhalation valve are no longer authorized for decontamination, according to the revised FDA EUA released June 6, 2020 https://www.fda.gov/media/136529/download.

Select VENUS Safety & Health N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[32]	Battelle CCDS™ Processable
Venus	N95, **V-4400**	**NO**	**YES**

Select Xiantao Zhongyi Safety Protection Products N95 processability using Battelle CCDS™

Manufacturer/ Supplier	Model	Known to contain cellulose[33]	Battelle CCDS™ Processable
Xiantao Zhongyi	N95, **ZB-11**	**NO**	**YES**

REFERENCES

[1] FDA Emergency Use Authorization for Battelle CCDS Critical Care Decontamination System™ Dated June 6, 2020 https://www.fda.gov/media/136529/download

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