

NIOSH Respiratory Protective Device Information

**NIOSH CA 2021-1033R1
June 2021**

Guidance for respirator users regarding NIOSH Approved surgical N95 filtering facepiece respirators (surgical N95s) exempt from 510(k) pre-market notification in accordance with the Food and Drug Administration regulations at 21 CFR § 878.4040.

Supersedes March 2021 version



**Centers for Disease Control
and Prevention**
National Institute for Occupational
Safety and Health

Subject: Guidance for respirator users regarding NIOSH Approved surgical N95 filtering facepiece respirators (surgical N95s) exempt from 510(k) pre-market notification in accordance with the Food and Drug Administration regulations at 21 CFR § 878.4040.

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Since August 24, 2020, the National Institute for Occupational Safety and Health (NIOSH) has accepted and prioritized approval applications for surgical N95 filtering facepiece respirators (surgical N95s), a subset of single-use disposable N95 filtering facepiece respirators (FFRs). **NIOSH-approved N95 FFRs are also regulated by the Food and Drug Administration (FDA) as class II devices under 21 CFR § 878.4040, classified as product code MSH, and commonly referred to as surgical N95s. This notice is intended to inform users about a subset of surgical N95s, exempted by regulation from the FDA's premarket notification (510(k)) requirements. This subset of NIOSH Approved surgical N95s are easily identified by the NIOSH approval labels, see Figures 1 and 2.**

NIOSH-approved surgical N95s offer the same level of respiratory protection as a NIOSH-approved N95 FFR. Additionally, the surgical N95 has demonstrated conformance to FDA specified flammability, fluid resistance, and biocompatibility requirements and is intended for use in all healthcare settings and for all medical purposes **in which an N95 level of respiratory protection is needed to protect the wearer.**

Users can recognize a **NIOSH-approved surgical N95 by the abbreviated label**, which is printed on each respirator. The surgical N95 abbreviated label includes the name of the approval holder (i.e., name of the company that was issued NIOSH approval), the model or part number, the approval number assigned by NIOSH (e.g., TC-84A-XXXX), **"Surgical N95 Respirator,"** "NIOSH," and the lot number. An example of an abbreviated label on a NIOSH-approved surgical N95 is shown in Figure 1 below.

The full NIOSH approval label, which is found on or within the respirator packaging, will indicate the protection type as being "Surgical/N95." An example of a NIOSH surgical N95 approval label is shown in Figure 2 below. The approval label will have the caution and limitation "S – Special or Critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning." The "S" caution and limitation will correspond to a section in the User Instructions that indicates, this respirator has been approved as a NIOSH N95 filtering facepiece respirator, for use in healthcare settings, as a Surgical N95 Respirator conforming to recognized standards for biocompatibility, flammability, and fluid resistance.

NIOSH-approved surgical N95s can be identified on the NIOSH [Certified Equipment List](#) (CEL) and can be searched using the term "surgical."

In addition to surgical N95s approved under the process described above, users can select and use a surgical N95 FFR that previously received NIOSH approval and [FDA 510\(k\) clearance](#). The User Instructions and packaging will include the caution and limitation “P – NIOSH does not evaluate respirators for use as surgical masks.” The abbreviated label, which is printed on the respirator, will also **not include** “surgical.” However, NIOSH can approve an approval holder’s updated User Instructions and packaging to **remove** the caution and limitation “P” and **include** caution and limitation “S.” The abbreviated label can also be updated to include “surgical.” It is expected that eventually all Surgical N95s will have consistent labeling and packaging as approval holders submit updates to NIOSH.

Surgical N95s exempt from the 510(k) premarket notification requirements must comply with applicable FDA labeling requirements and all other statutory and regulatory requirements. When the labeling and packaging is updated, these surgical N95 FFRs can also be found on the CEL by using the term “surgical.”

Figure 1: Example of an abbreviated label on a NIOSH Approved surgical N95

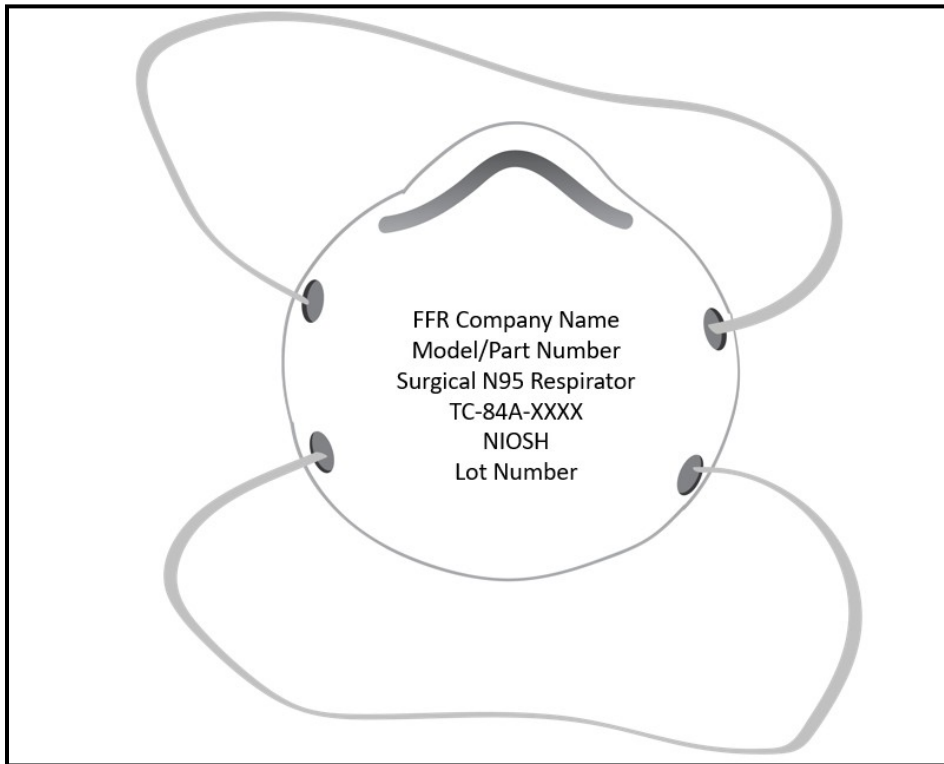




Figure 2: Example of a NIOSH surgical N95 full respirator approval label, often located on or within the packaging.



SURGICAL N95 MANUFACTURING
2020 Respirator Avenue
ANYWHERE, PA USA
1-800-123-4567



THESE RESPIRATORS ARE APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS			
TC-	Protection ¹	Respirator	Cautions and Limitations ²
		NEW2020	
84A-XXXX	Surgical/N95	X	ABCJMNOS

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% 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.
 S – Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

REFERENCES:

[FDA Final Order](#)

[FDA Postmarket Requirements \(Devices\)](#)

[Approval of Respiratory Protective Devices, 42 CFR Part 84](#)

[MOU 225-18-006](#)

[NIOSH Conformity Assessment Letter to Manufacturers \(CA 2018-1010R1\) | NPPTL | NIOSH | CDC](#)

[NIOSH Conformity Assessment Letter to Manufacturers \(CA 2020-1031\) | NPPTL | NIOSH | CDC](#)

Revision (R)	Date	Reason for Revision
1.0	12 May 2021	NIOSH revised this notice based on HHS review and comments.