

Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the STERIZONE VP4 Sterilizer Using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle in STERIZONE VP4 Sterilizers (referred to as “STERIZONE VP4 Sterilizer”) manufactured by TSO3, Stryker Instruments, for use in decontaminating compatible N95 respirators in a healthcare facility for single-user reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. Compatible N95 respirators are any non-cellulose containing respirators that do not have an exhalation valve, antimicrobial agents, or a duck-billed design and that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at <https://www.fda.gov/emergency-preparedness-and-response/mcmlegal-regulatory-and-policy-framework/emergency-use-authorization>. Please see FDA’s website for further information on N95 respirators, available at <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks>.

Healthcare personnel (HCP) should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle in the STERIZONE VP4 Sterilizer.

The STERIZONE VP4 Sterilizer has neither been cleared or approved by FDA, but has been authorized by FDA under an EUA for use in decontaminating compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during the COVID-19 outbreak. The emergency use of the STERIZONE VP4 Sterilizer is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, under section 564(b)1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Respirators that are NIOSH-approved before decontamination (<https://wwwn.cdc.gov/niosh-cel/>) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated NIOSH-approved respirator, please check with the respirator manufacturer and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.



The Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle in the STERIZONE VP4 Sterilizer is not authorized for use with the following:

- Respirators containing cellulose-based materials;
- Respirators containing antimicrobial agents;
- Respirators with duck-billed designs;
- Respirators containing exhalation valves; and
- Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.

HCP must perform a user seal check of the decontaminated, compatible N95 respirator according to OSHA standards prior to beginning a shift. If the user seal check does not pass, discard the respirator.

Discard compatible N95 with visible soiling (e.g., blood, dried sputum, makeup, soil) or damage – do not use and do not send for decontamination.

Decontaminated compatible N95 respirators are not sterile.

Compatible N95 respirators may be decontaminated up to 2 times.

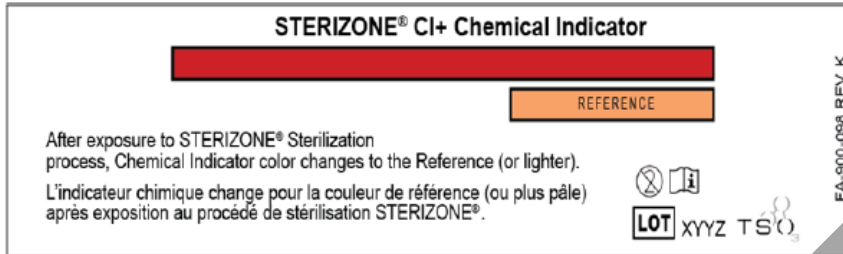
Any compatible N95 respirator with illegible markings to indicate the number of decontamination cycles completed must be discarded.

Compatible N95 Respirator Marking and Collection

1. Pouch your own individual compatible N95 respirator at the end of use and label with your name or other identifier using a permanent marker; do not label others' or ask others to label for you. **NOTE:** Labeling should be legibly written on the outside OR inside of each compatible N95 respirator, as shown below.
2. Place a tick mark on your compatible N95 respirator to maintain the decontamination

cycle count. **NOTE:** Your compatible N95 respirator may be decontaminated a **maximum of two (2) times.**

- Place your compatible N95 respirator in the Tyvek pouch provided by your healthcare facility at a designated collection station, ensure that a STERIZONE CI+ chemical indicator strip is contained within the pouch, and seal it. The chemical indicator strip should look like this:



- After receiving your decontaminated, compatible N95 respirator, please check the respirator to ensure you are the appropriate individual. If the labeling is not legible, there is visible soil, or the respirator is damaged or wet, the respirator must be discarded. Ensure that the chemical indicator strip (color strip at the top) has changed to be equal to or lighter than the reference color. Please perform a user seal check of the decontaminated, compatible N95 respirator according to OSHA standards prior to beginning a shift. If the user seal check does not pass, discard the respirator.

NOTE: Collection bags are for compatible N95 respirators only; do not throw other personal protective equipment (such as gloves), paper towels, or waste in the collection bags.

Example of compatible N95 respirator marked with user's name and location



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