

Instructions for Healthcare Personnel: Emergency Use of Sterilucent Sterilization System to Decontaminate Compatible N95 Respirators

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Sterilucent HC 80TT Vaporized Hydrogen Peroxide Sterilizer (hereafter referred to as the “Sterilucent Sterilization System”) to be used on the Sterilucent N95 Respirator Decontamination Cycle (“Flexible” Pre-Programmed Sterilization Cycle) for use in decontaminating compatible N95 respirators for single-user reuse by healthcare personnel. 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 should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination using the Sterilucent Sterilization System.

The Sterilucent Sterilization System 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 Sterilucent Sterilization System 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 Sterilucent Sterilization System 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.
- Use proper hand hygiene and gloves when removing or handling potentially contaminated N95 respirators.
- All compatible N95 respirators used in the Sterilucent Sterilization System must be free of visible damage, visual soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids), and excessive odor.
- Discard and do not collect compatible N95 respirators that are visually soiled or damaged.
- Each compatible N95 respirator will be individually packaged in a Tyvek Self-seal pouch, or equivalent pouch.
- Discard the compatible N95 respirator after exceeding 4 decontamination cycles.
- Discard any compatible N95 respirator whose traceability was lost or number of decontamination cycles was not able to be identified.
- Decontaminated, compatible N95 respirators are not sterile.

Compatible N95 Respirator Marking and Collection:

1. Sterilucient, Inc. recommends maintaining chain of custody on the compatible N95 respirators to minimize the risk of cross-contamination. Pouch your own individual compatible N95 respirator in Tyvek® pouches at the end of use. Label with your name and/or other identifier using a permanent marker. Labeling should be legibly written on the outside or inside of each compatible N95 respirator, as shown (see **Figure 1**: Chain of custody identification of compatible N95 respirators).



Figure 1: Chain of custody identification of compatible N95 respirators

- Place a tick mark on your compatible N95 respirator each time to maintain the decontamination cycle count, using a permanent marker. **NOTE: Your respirator may be decontaminated a maximum of 4 times.**
2. Confirm that the labeling is legible, and that there is no visible damage, including low restorative strap performance, soil/contamination, or excessive odor, prior to pouching the compatible N95 respirator.
 3. Place your compatible N95 respirator in the Tyvek pouch, or equivalent, provided by your healthcare facility and seal it. Place the pouched, compatible N95 respirator at the healthcare facility's designated collection station.

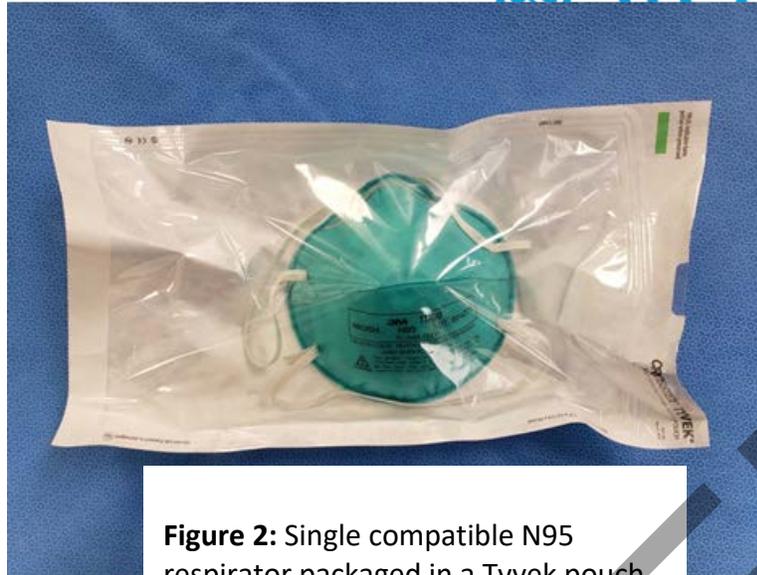


Figure 2: Single compatible N95 respirator packaged in a Tyvek pouch

4. After receiving your decontaminated, compatible N95 respirator, please check the respirator to ensure you are the appropriate individual. Please perform a user seal check according to OSHA standards prior to beginning a shift. If the user seal check does not pass, discard the respirator.
5. If at any time the labeling is not legible or there is visible soil or damage, discard the respirator. Discard the respirator after 4 decontamination cycles.

NOTE: Only compatible N95 respirators in Tyvek, or equivalent, pouches may be placed at this collection station for decontamination. No other items will be decontaminated in the same decontamination cycle.