

Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination Using the STERIS Sterilization Systems

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of the STERIS N95 Respirator Decontamination Cycle (Non Lumen Cycle) in STERIS V-PRO 1 Plus, maX, maX 2, 60 and s2 Sterilizers (hereafter referred to as the “STERIS Sterilization Systems”) for use in decontaminating compatible N95 or N95-equivalent respirators (hereafter referred to as “compatible N95 respirators”), for single-user reuse by healthcare personnel. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination using the STERIS Sterilization System.

The STERIS Sterilization Systems have been authorized by FDA under an EUA for decontamination of compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates. The STERIS Sterilization Systems have not been cleared or approved for this use. The STERIS Sterilization Systems are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices unless the authorization is terminated or 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.

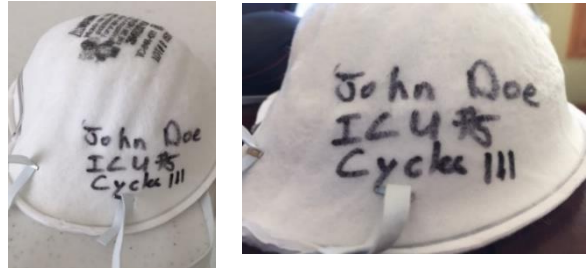


- **The STERIS Sterilization Systems are not authorized for use with the following:**
 - o Respirators or pouches containing cellulose-based materials;
 - o Respirators containing exhalation valves; and
 - o Respirators containing antimicrobial agents;
 - o Respirators with duck-billed designs; and
 - o Respirators that are authorized in the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.
- All compatible N95 respirators used in the STERIS Sterilization Systems must be free of visible damage and soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids).
- Do not collect compatible N95 respirators that are visually soiled or damaged for decontamination and discard such respirators.
- Discard compatible N95 respirators after exceeding 4 decontamination cycles.
- Discard any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified.
- Decontaminated, compatible N95 respirators are not sterile.

Compatible N95 Respirator Marking and Collection:

1. STERIS 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. You should 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 below.

- Place a tick mark on your compatible N95 respirator and Tyvek pouch each time to maintain the decontamination cycle count. **NOTE: your respirator and Tyvek pouch may be decontaminated up to a maximum of 4 times.**



- Confirm that the labeling is legible, and that there is no visible damage or soil/contamination prior to pouching the compatible N95 respirator.
- Place your compatible N95 respirator in the Tyvek pouch provided by your healthcare facility and seal it. Place the pouched, compatible N95 respirator at the healthcare facility's designated collection station.
- After receiving your decontaminated, compatible N95 respirator, please check the respirator to ensure you are the appropriate individual.
- If at any time the labeling is not legible or there is visible soil or damage, discard the respirator. Discard the respirator and Tyvek pouch after 4 decontamination cycles.

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