

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

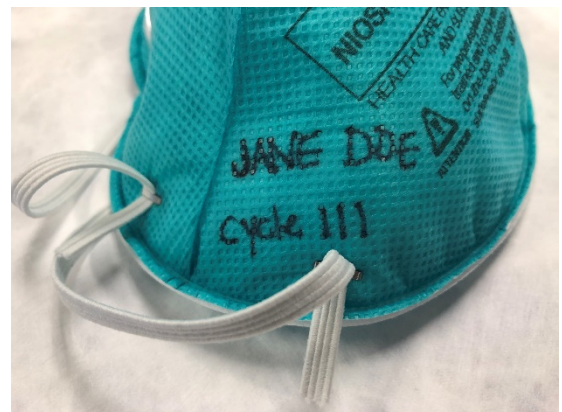
The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Sterilucient HC 80TT Vaporized Hydrogen Peroxide Sterilizer (hereafter referred to as the “Sterilucient Sterilization System”) to be used on the Sterilucient N95 Respirator Decontamination Cycle (“Flexible” Pre-Programmed Sterilization Cycle) 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 Sterilucient Sterilization System.



- **Due to incompatibility, the Sterilucient Sterilization System is not authorized for use with respirators or pouches containing cellulose-based materials.**
- **Use proper hand hygiene and gloves when removing or handling potentially contaminated N95 respirators.**
- **All compatible N95 respirators used in the Sterilucient Sterilization System must be free of visible damage, soil/contamination (e.g. blood, dried sputum, makeup, soil, bodily fluids), and excessive odor.**
- **Compatible N95 respirators that are visually soiled or damaged should not be collected for decontamination and should be discarded.**
- **Each compatible N95 respirator should be individually packaged in a Tyvek Self-seal pouch, or equivalent pouch.**
- **Compatible N95 respirators should be discarded after 10 decontamination cycles.**
- **Any compatible N95 respirator whose traceability was lost or number of decontamination cycles was not able to be identified should be discarded.**
- **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. 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 (see **Figure 1** below: Chain of Custody identification of N95 compatible respirators).
2. Place a tick mark on your compatible N95 respirator and Tyvek pouch each time to maintain the decontamination cycle count, **using a permanent marker**. **NOTE: Your respirator and Tyvek pouch may be decontaminated up to a maximum of 10 times.**
3. 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.
4. 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.

5. After receiving your decontaminated, compatible N95 respirator, please check the respirator to ensure you are the appropriate individual.
6. 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 10 decontamination cycles.



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

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