

Instructions for Healthcare Personnel: Preparation of Compatible N95 or N95-equivalent 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 authorized an Emergency Use Authorization (EUA) for the emergency use of the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle in STERIZONE VP4 Sterilizers manufactured by TSO3, a Stryker Instruments, for use in decontaminating compatible N95 or N95-equivalent respirators (hereafter referred to as the “compatible N95 respirators”) in a healthcare facility for single-user reuse by healthcare personnel. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare N95 respirators for decontamination using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle.



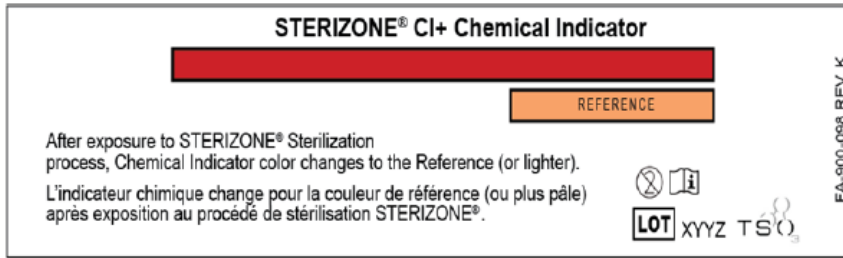
Due to incompatibility, the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle is not authorized for use with respirators containing cellulose-based or paper materials, natural rubber, or latex.

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 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 reprocessing cycle count. **Note:** your N95 respirator may be decontaminated a **maximum of two (2) times**.
3. 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:



4. 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 should be discarded. Check to make sure that the chemical indicator strip (color strip at the top) has changed to be equal to or lighter than the reference color. It is recommended to perform an evaluation of the N95 respirator facial fit after decontamination following the recommendation of the manufacturer, or the facility policy.

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 N95 mask marked with user name and location

