

Instructions for Healthcare Personnel:

Preparation and Collection of Compatible N95 Respirators for Decontamination by Roxby Development Using the Zoe-Ann Decontamination System

*These respirators have been decontaminated to deactivate the SARS-CoV-2 virus, but they are not sterile.

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of Roxby Development's Zoe-Ann Decontamination System (hereafter referred to as the "Z-A Decon System") for use in decontaminating compatible N95 respirators for single-user reuse (i.e., the same respirator is returned for reuse to the same healthcare personnel following its decontamination) by healthcare personnel. Healthcare personnel must follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination by Roxby Development using the Z-A Decon System.

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 Z-A Decon System is not authorized for use with:**
 - Respirators containing cellulose-based or paper materials;
 - Respirators containing exhalation valves;
 - Respirators containing antimicrobial agents;
 - Respirators with duck-billed designs; and
 - Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.
- **Healthcare personnel must perform a user seal check of the decontaminated, compatible N95 respirator according to OSHA standard prior to beginning a shift. If the user seal check does not pass, discard the respirator.**
- **All compatible N95 respirators provided to Roxby Development must be free of any visual soiling or contamination (e.g., blood, bodily fluids, makeup).**
- **Discard and do not collect any compatible N95 respirators that are visually soiled or damaged.**
- **Any compatible N95 respirator whose traceability is lost, or the number of decontamination cycles cannot be identified must be discarded.**
- **Discard compatible N95 respirators after four (4) decontamination cycles.**
- **Decontaminated, compatible N95 respirators are not sterile.**
- **Do not use decontaminated, compatible N95 respirators during surgical procedures.**
- **The Z-A Decon System is not FDA-cleared or approved, but has been authorized by FDA under an EUA for the decontamination of compatible N95 respirators for single-user reuse**

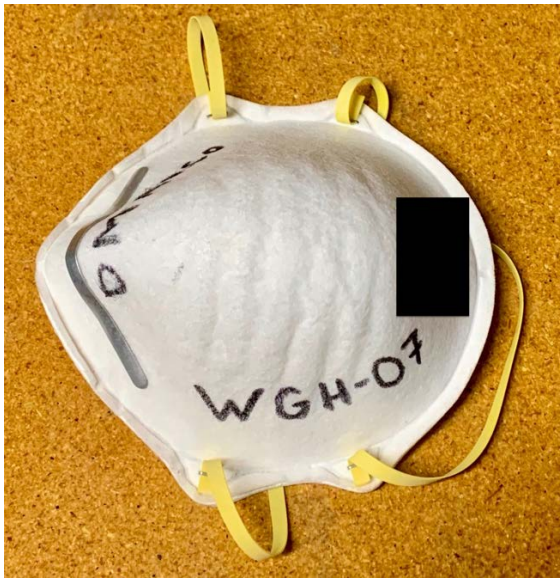


by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates.

- The Z-A Decon 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 unless the authorization is terminated or revoked sooner.

Compatible N95 Respirator Marking and Collection:

1. Label your own individual compatible N95 respirator using a permanent marker (some respirator material may be degraded by felt tip markers); do not label others' respirators.
2. Labeling will be legibly written on the outside OR inside of each compatible N95 respirator, as shown below.
3. Label ALL compatible N95 respirators with the three-digit facility code and 2-digit unit code provided below.
4. Place your compatible N95 respirator in the collection bin at the designated collection station for your unit. Each collection bin can hold 50-80 respirators dropped in loosely.
5. Hospital personnel will collect and seal the biohazard containers, spray the entire exterior with alcohol or other approved sterilizer, and hold in a secure location for Roxby Development logistics staff to pick up.



Facility Code

Unit Code

Compatible N95 respirator with 3-digit facility code and 2-digit unit code with number of decontamination cycles noted on the strap (red circle)