

## Instructions for Healthcare Facilities:

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

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). 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.

All personnel involved in the collection and distribution of decontaminated respirators and those using the decontaminated respirators will be regularly screened in accordance with the healthcare facility's procedures.

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.



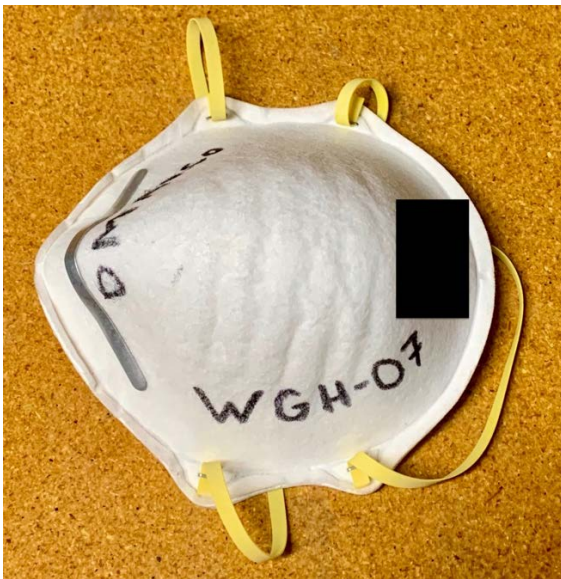
- **The Z-A Decon System is not authorized for use with:**
  - Respirators containing cellulose-based or paper materials;
  - Respirators containing exhalation valves;
  - Respirators containing antimicrobial agents;
  - Respirators with duck-billed designs; and
  - Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.
- All compatible N95 respirators provided to Roxby Development must be free of any visual soiling or contamination (e.g., blood, bodily fluids, makeup).
- Do not collect compatible N95 respirators that are visibly soiled or damaged for decontamination. Any visibly soiled or damaged respirators that have been collected will be disposed of by Roxby Development.
- Discard compatible N95 respirators after exceeding four (4) decontamination cycles.
- Decontaminated, compatible N95 respirators are not sterile.
- 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.

**On-Site Collection/Marking:**

1. Create a collection station at the point of generation (i.e., hospital floor/unit).
2. Each station will have a plastic bin provided by Roxby Development to collect compatible N95 respirators.

**NOTE: Bins are for compatible N95 respirators only. Do not throw other personal protective equipment such as gloves, paper towels, or waste in the collection bag.**

3. With a permanent marker, the healthcare personnel label their own individual compatible N95 respirators with a three-digit facility code and a 2-digit unit code on the outside of the respirator (as shown below). The unique facility code corresponds to the healthcare facility delivery address and will be assigned by Roxby Development. Your organization may designate the unit code to correspond to a specific location/floor/unit within your site.
4. Healthcare personnel must follow the instructions provided by Roxby Development in Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by Roxby Development's Zoe-Ann Decontamination System.



**Facility Code**

**Unit Code**

**(Assigned by Roxby Development)**

**(Assigned by Facility)**

**Preparation for Shipment:**

1. Close and seal bins containing the contaminated, compatible N95 respirators to be decontaminated by Roxby Development.
2. Decontaminate the collection bin with alcohol or another suitable decontaminant.
3. Ensure the label on the bin with a biohazard symbol is still intact.
4. Write your initials, personnel number, and date on the Roxby Development provided labels and tape 2 sides of the bin's airtight seal as a tamper barrier.

5. Label the outside of the box with the 3-digit facility code and 2-digit unit code (if original label has worn or is missing).

**Shipment under the healthcare facility's agreement with Roxby Development:**

1. Gather all bins; complete one chain of custody form (provided by Roxby Development) per shipment, noting the number of bins.
2. Contact your organization's courier service or Roxby Development to arrange transfer to Roxby Development's site for the Z-A Decon System. **\*\*\*Roxby Development recommends storing bins in a locked location that will not be disrupted while awaiting pickup\*\*\***

**Reuse Information:**

Following decontamination, you will be provided **decontaminated, compatible N95 respirators** that have been processed through a decontamination system for single-user reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic. Before reuse, the healthcare facility must review the chain of custody form, which indicates successful decontamination, accompanying the returned respirators. The healthcare facility must also inspect each returned, decontaminated, compatible N95 respirator for:

1. Lined indication of the decontamination cycle number found on the strap. **NOTE: Compatible N95 respirators will be disposed of after four (4) decontamination cycles.**
2. Visible damage or soiling. **NOTE: Compatible N95 Respirators must be discarded and not reused if visually damaged or soiled.**

**Any problems should be immediately reported to Roxby Development.**

**Roxby Development Contact: 1-800-921-4163 or [zadecon@roxbydevelopment.com](mailto:zadecon@roxbydevelopment.com)**