HEALTHCARE

Bioquell Hydrogen Peroxide Vapor Technology

for the Decontamination of N95 Respirators

The U.S. Food and Drug Administration has granted Bioquell a temporary Emergency Use Authorization (EUA) for decontaminating compatible N95 respirators* with the use of Bioquell 35% hydrogen peroxide vapor technology.

Existing customers can apply their current Bioquell system(s) to perform this task, and new clients can be quickly trained to operate Bioquell equipment safely and efficiently.

The following Bioquell systems are approved for this application during the length of the granted EUA: Bioquell BQ-50 and Bioquell ProteQ.

Key Facts:

- Each respirator can be decontaminated up to 4 times
- Only the following compatible respirators may be decontaminated: 3M N95 respirator models: 1860, 8210, 1804, and 1870+
- Cellulose-based materials should be considered incompatible with the Bioquell decontamination process
- Respirators with visible soiling (e.g., blood) or damage must be discarded
- While Bioquell will offer insights, healthcare facilities are responsible for the coordination, tracking, reporting and safety of all respirators
- Recent studies from Duke Health and Yale University utilized Bioquell systems to effectively reprocess N95 respirators while ensuring the integrity of the mask was retained
- Bioquell hydrogen peroxide vapor produces a 6 $\log_{10}$ sporicidal kill on all exposed surfaces
- The Bioquell Technology System is authorized only for the duration of the COVID-19 pandemic declaration, unless the authorization is terminated or revoked sooner

For more information, visit **bioquell.com/N95**

PLEASE NOTE

*N95 or N95-equivalent respirators containing cellulose-based materials are incompatible with the Bioquell decontamination process.

The Bioquell technology system has neither been cleared nor approved for the indication to treat patients with COVID-19 infection.

The Bioquell System has neither been cleared nor approved for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates.

The Bioquell System has been authorized by FDA under an EUA200348.

The Bioquell System is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

USE BIOQUELL PRODUCTS SAFELY. ALWAYS READ THE LABEL AND PRODUCT INFORMATION BEFORE USE.

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