



NEWS RELEASE

FDA Authorizes Ecolab's Bioquell Technology System for N95 Respirator Decontamination

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Ecolab's decontamination technology enables respirator reuse by healthcare personnel to help address shortages

ST. PAUL, Minn.--(BUSINESS WIRE)-- Ecolab Inc., the global leader in water, hygiene and infection prevention solutions and services that protect people and vital resources, has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its Bioquell Technology System to decontaminate specific N95 respirators.¹ The EUA is for Ecolab's Bioquell BQ-50 and Bioquell ProteQ decontamination systems and enables healthcare facilities to decontaminate respirators on-site to help address continuing respirator shortages.

Leveraging Ecolab's leading decontamination expertise providing solutions that help prevent hospital-acquired infections in critical care areas and help ensure pharmaceutical manufacturing cleanrooms remain sterile, the Bioquell Technology System uses a proprietary hydrogen peroxide vapor technology for respirator decontamination.

"As healthcare facilities continue to experience shortages of respirators amidst a surge in COVID-19 cases in the United States, and with large-scale vaccination on the horizon, the ability to reuse this essential personal protective equipment brings additional protection to frontline workers," said Elizabeth Simermeyer, Ecolab executive vice president and president, Global Healthcare and Life Sciences. "This Emergency Use Authorization from the FDA gives healthcare facilities added flexibility to confidently deploy Bioquell technology to decontaminate respirators on-site."

Using Ecolab's Bioquell Technology System, specified N95 masks can be decontaminated up to four times for reuse by healthcare professionals to help prevent exposure to airborne pathogenic particulates. This proprietary system



creates a hydrogen peroxide vapor technology that eliminates pathogens from every exposed surface within an enclosed area, providing a 99.9999% reduction of bioburden (6 log₁₀ sporicidal kill).

This technology is used in life science product manufacturing facilities and in healthcare facilities throughout the world to eliminate harmful organisms and emerging pathogens in operating rooms, critical care areas, patient rooms and ambulances. In Canada, Health Canada has granted a similar emergency authorization for Ecolab's Bioquell Technology System for respirator decontamination.

Bioquell's technology for the decontamination of N95 respirators has been the subject of several studies, including studies by Duke University Health System², Yale University³ and the U.S. Air Force Research Laboratory and National Institute for Occupational Health & Safety (NIOSH).⁴ Ecolab and Bioquell will provide healthcare facilities with guidance, training and technical support to reprocess N95 masks using Bioquell technology, consistent with the process outlined in the FDA Emergency Use Authorization and information published by **Duke University Health System**. The FDA previously granted EUAs for decontamination systems utilizing Bioquell hydrogen peroxide vapor technology and services to collect and return decontaminated respirators to selected healthcare facilities.

For more information on Ecolab's Bioquell Technology System including the FDA's emergency use authorization for the decontamination of N95 respirators, visit www.bioquell.com/N95.

Ecolab's Bioquell Technology System has neither been cleared nor approved by FDA, but has been authorized for emergency use by FDA under an EUA for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates. The emergency use of Ecolab's Bioquell Technology 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, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

About Ecolab

A trusted partner at nearly 3 million commercial customer locations, Ecolab (NYSE:ECL) is the global leader in water, hygiene and infection prevention solutions and services. With annual sales of \$13 billion and more than 45,000 associates, Ecolab delivers comprehensive solutions, data-driven insights and personalized service to advance food safety, maintain clean and safe environments, optimize water and energy use, and improve operational efficiencies and sustainability for customers in the food, healthcare, hospitality and industrial markets in more than 170 countries around the world. www.ecolab.com.

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¹ FDA limits Bioquell Emergency Use Authorization to 3M N95 respirator models: 1860, 8210, 1804, and 1870+.

² Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor to Address Worldwide Personal Protective Equipment Shortages During the SARS-CoV-2 (COVID-19) Pandemic:

https://dicon.medicine.duke.edu/sites/dicon.medicine.duke.edu/files/duke_n-95_vhp_decon_re-use_pdf.pdf

³ Hydrogen Peroxide Vapor sterilization of N95 respirators for reuse:

<https://www.medrxiv.org/content/10.1101/2020.03.24.20041087v1>

⁴ Evaluation of Multiple (3-Cycle) Decontamination Processing for Filtering Facepiece Respirators:

<https://digitalcommons.unl.edu/usafresearch/105/>

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