IMPORTANT NOTICE

FDA REVOKES AUTHORIZATION FOR THE USE BY HEATH CARE PERSONNEL IN HEALTH CARE SETTINGS OF DEVICES TO DECONTAMINATE NIOSH-APPROVED DISPOSABLE RESPIRATIORS

Effective June 30, 2021 due to the increased domestic supply of NIOSH approved respirators the FDA is revoking the Emergency Use Authorization ("EUA") granted to manufacturers of decontamination and bioburden reduction systems.

In their UPDATE notice, FDA recommends several NIOSH-approved respirator strategies to transition from previously recommended "crisis capacity conservation strategies".

See full text of FDA's announcement at the link below:

https://www.fda.gov/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-or-decontaminated-disposable-respirators

Specifically, regarding the use of the N95 software package incorporated into the RH-Pro9 and RH-Pro11 sterilizers, this designated N95 cycle is no longer authorized to be used by the specific revocation of "Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators During the Coronavirus Disease (2019) Public Health Emergency "under which its use was permitted.

Any use of the N95 cycle for decontamination of N95 masks by the operator of your RH-Pro9 or RH-Pro11 sterilizer becomes the responsibility of the operator and the owner of that equipment. Please note that CPAC Equipment, Inc. bears no responsibility for the operator's or the owner 's actions regarding N95 cycle use during periods of FDA non-authorization.

If conditions change and N95 respirators are again in short supply due to the continuance of the Covid-19 pandemic and/or any new public emergency, FDA will re-evaluate the situation and may issue new or reinstate previous EUA's to address the shortages. If any new pertinent or reinstated EUA's regarding the use of our N95 software are issued, you will be alerted through our website at cpac.com.

Thank you.

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