

## **STATEMENT ON THE PERMITTED USE OF THE RH-N95 FOR N95 RESPIRATOR DISINFECTION UNDER FDA EMERGENCY AUTHORITY**

High-Velocity Hot Air Sterilizers (Cox RapidHeat Transfer) were originally granted 510(k) status (clearance to market) from the U. S. Food and Drug Administration (FDA) in 1987/1988 as a Class II (Performance Standards) device. The RH-Pro series of sterilizers is a size modification of the original Cox Sterilizer and meets Section 513(i) of the FD&C Act and 21 CFR 807.100(b) which states that, for a new device to be considered substantially equivalent to a predicate device, the new device must have the same intended use as the predicate device and the same technological characteristics or different technological characteristics that do not raise different questions of safety and effectiveness than the predicate device. Meeting FDA's criteria, RH-Pro series of HVHA sterilizers retains its clearance under the original 510(k) clearance.

On March 29, 2020 FDA issued their notice entitled "Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" that states:

*"During the declared public health emergency, FDA does not intend to object to the distribution and use of sterilizers, disinfectant devices, and air purifiers that are intended to be effective at killing the SARS-CoV-2 virus but do not already have FDA marketing authorization ..., where such devices do not create an undue risk in light of the public health emergency." "FDA believes such devices will not create such an undue risk where the performance and labeling elements in Sections IV.A and IV.B, respectively, are met."*

### Section IV.A "Sterilizers" requirements applicable to dry heat:

*"For the purposes of this guidance, FDA recommends any modifications, including changes to the indications or functionality, to sterilizers and their accessories be designed, evaluated and validated in accordance with FDA-recognized 16 standards, including (as applicable):*

#### *Dry Heat Sterilizers*

- *AAMI ST50:2004 (R2018) Dry Heat (Heated Air) Sterilizers*
- *ANSI/AAMI ST40:2004m (R2018) Table-Top Dry Heat (Heated Air) Sterilization and Sterility Assurance in Health Care Facilities"*

### Section IV. B "Labeling "requirements:

*"FDA recommends that the devices described above include labeling that helps users better understand the device modifications, such as*

- (1) A clear description of the available data on the device's new indications or functions related to SARS-CoV-2 or co-existing conditions, such as:
  - a) Device performance; and*
  - b) Potential risks (e.g., risk of UV exposure)**
- (2) A clear distinction delineating FDA-cleared or FDA-approved indications from those that are not FDA-cleared or FDA-approved. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA."*

Peer review literature research has provided CPAC Equipment with the documentation that the RH-N95 can meet or exceed > 6Log reduction of coronavirus (or its surrogate) and that of Mycobacterium and while assuring respirator performance standards are met for a re-used mask. The RH-N95 decontamination unit meets the criteria for market clearance under FDA's guidance document criteria.