

**Dear Valued Customer:**

The US Food and Drug Administration notified STERIS that the FDA is reissuing the June 6<sup>th</sup>, 2020 EUA letter for the STERIS Low Temperature Sterilization System (V-PRO maX, maX2, 60, S2) and the May 21<sup>st</sup>, 2020 EUA letter for the STERIS STEAM Decon Cycle (AMSCO® 400 or AMSCO® Century Medium Steam Sterilizer) to include the following changes:

1. Limitation/revision of the **“compatible N95 respirators”** which the decontamination system is authorized to decontaminate
2. Limitation of the maximum number of decontamination cycles to **four (4) cycles** per compatible N95 respirator
3. Request for additional in use/real world evidence (RWE) for fit, filtration and marking of respirators as an additional condition for maintaining the EUAs

For V-PRO Sterilizer use, the FDA has defined **“compatible N95 respirators”** as **any non-cellulose containing respirators that do not have an exhalation valve, antimicrobial agents, or a duck-billed design, and that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (see the STERIS COVID-19 Landing Page for the EUA).**

For use of the STERIS Steam Decon Cycle, the FDA has defined **“compatible N95 respirators”** as **the 3M 8210, 3M 1860, 3M 1860S, and 3M 1805 NIOSH-approved N95 respirators only.**

The transition to these conditions (e.g 4 cycles) is being applied to all decontamination EUAs currently issued by FDA.

STERIS is not aware of, either by Customer notification or publication in literature, of any specific issues with either the V-PRO Sterilizer or STERIS Steam Decon Cycle when used to decontaminate compatible N95 respirators.

STERIS is currently evaluating the requirements for additional RWE testing as provided by FDA.

If you have any questions, please [contact your STERIS Account Manager and/or Clinical Specialist](#). You can also visit the updated STERIS [COVID-19 landing page](#) with the following resources available:

- Emergency Use Authorizations
- Healthcare Facility & Personnel Instructions
- Fact Sheets
- Customer Q&A's
- Customer Letters

STERIS remains committed to your success in delivering patient care through this pandemic. Thank you for all that you are doing to serve your patients.

Best Regards,

STERIS Infection Prevention Technologies