**URGENT MEDICAL DEVICE NOTICE**
**Emergency Use Authorization Revocation for V-PRO® Low Temperature Sterilization Systems**

July 30, 2021

**ATTN: QUALITY MANAGEMENT OR STERILE PROCESSING DEPARTMENT**

Dear Valued STERIS Customer:

In response to the COVID-19 pandemic, STERIS requested, and was granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) for the emergency use of the STERIS V-PRO® 1 Plus, V-PRO® maX, V-PRO® maX2, V-PRO® 60, and V-PRO® s2 Low Temperature Sterilization Systems to decontaminate compatible N95 or N95-equivalent respirators for single-user reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of N95 respirators. This EUA was issued on April 9, 2020, and revised and reissued on June 6, 2020, and January 21, 2021.

**Effective June 30, 2021, FDA has revoked STERIS's EUA for the STERIS V-PRO Low Temperature Sterilization Systems making them no longer authorized for emergency use**.

Based on the increased supply of respirators, the Centers for Disease Control and Prevention's (CDC) updated recommendations, and in alignment with the Occupational Safety and Health Administration's (OSHA) recently published Emergency Temporary Standards, FDA has determined that it is appropriate to revoke this authorization. STERIS has notified FDA that it has ceased operations and associated activities which support the decontamination and re-use of N95 respirators.

In International markets, STERIS submitted this information to a number of Competent Authorities across the European Union and also to a number of regulatory authorities outside of Europe. These submissions were not a request for local authorisation to approve the process, but more to inform them of a new reprocessing method validated by STERIS and a major respirator manufacturer, in this case 3M®, and to update them on the US FDA's EUA granted to STERIS. We provided this information as a responsible manufacturer, to allow healthcare facilities and those Competent Authorities to be able to make informed decisions regarding respirator performance after reprocessing in exceptional circumstances, due to the shortage of supply experienced for respirators.

It is vital that any activities that have been occurring based on the previously approved EUA are ceased immediately. Healthcare facilities should follow updated guidance from applicable authorities regarding the use of NIOSH approved N95 respirators. STERIS's V-PRO Low Temperature Sterilization Systems shall only be used according to applicable clearance within the jurisdiction for terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities and shall no longer be used for decontamination of compatible N95 or N95-equivalent respirators.

STERIS would like to take the opportunity to thank our frontline healthcare workers for their sacrifice and commitment and are honored to have supported them during these unprecedented times. If you any have questions regarding this letter, please contact Andy Sutcliffe, Senior Director of IPT Marketing EMEA, STERIS Customer Service or your local STERIS Representative.

Regards,

Andy Sutcliffe
Senior Director of Marketing EMEA - Infection Prevention Technologies
STERIS
andy_sutcliffe@steris.com