June 30, 2021

Dr. Brodbeck
Senior Director, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Re: Revocation of EUA

Dear Dr. Brodbeck:

This letter is in response to STERIS Corporation's (STERIS's) request dated May 13, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the V-PRO 1 Plus, V-PRO maX, V-PRO maX2, V-PRO 60, and V-PRO s2 models of the vaporized hydrogen peroxide (VHP) low temperature sterilization systems (hereafter referred to as "STERIS Decontamination Systems") issued on April 9, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. STERIS will no longer make the STERIS Decontamination Systems available for the authorized emergency use. In its request, STERIS confirmed that it has ceased operation of all STERIS Decontamination Systems sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because STERIS has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of these systems, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes STERIS's EUA for the STERIS Decontamination Systems, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the STERIS Decontamination Systems are no longer authorized for emergency use by FDA.

FDA encourages STERIS to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration