June 30, 2021

Peter Kalkbrenner
Sterilucent, Inc.
1400 Marshall Street NE
Minneapolis, MN 55413

Re: Revocation of EUA

Dear Mr. Kalkbrenner:

This letter is in response to Sterilucent, Inc.'s (Sterilucent's) request dated April 15, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (hereafter referred to as "Sterilucent Decontamination System") issued on April 20, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. Sterilucent will no longer make the Sterilucent Decontamination System available for the authorized emergency use. In its request, Sterilucent confirmed that it has ceased operation of all Sterilucent Decontamination System 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 Sterilucent 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 this system, 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 Sterilucent's EUA for the Sterilucent Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Sterilucent Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Sterilucent 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