



June 30, 2021

Moira Barton-Varty, RAC
Senior Principal Regulatory Affairs
Stryker Sustainability Solutions
1810 West Drake Drive
Tempe, AZ 8528

Re: Revocation of EUA

Dear Ms. Barton-Varty:

This letter is in response to Stryker Sustainability Solution's (SSS's) request dated May 25, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Stryker Sustainability Solutions VHP N95 Respirator Decontamination System (hereafter referred to as "SSS Decontamination System") issued on May 27, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. SSS will no longer make the SSS Decontamination System available for the authorized emergency use. In its request, SSS confirmed that it has ceased operation of all SSS 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 SSS 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 SSS EUA for the SSS 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 SSS Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages SSS 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