August 10, 2026

Maud Humbert
Sr. Manager, Global Regulatory Affairs
Vantive US Healthcare LLC
510 Lake Cook Road
Deerfield, IL 60015

Re: Revocation of EUA200704

Dear Maud Humbert,

This letter is in response to the request from Vantive US Healthcare LLC in a letter received January 9, 2026, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Prismaflex ST Sets (EUA200704) issued on May 20, 2020. Vantive US Healthcare LLC included in the revocation request a change of ownership statement advising FDA that Vantive US Healthcare took ownership of EUA200704 from Baxter Healthcare with an effective date of February 1, 2025. In email correspondence dated August 3, 2026, Vantive Healthcare confirmed that there are no EUA devices within expiry remaining in distribution, as the last manufacturing lot expired on September 30, 2024. Further, FDA cleared the Prismaflex ST Sets under K212216 on April 1, 2022.

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, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Vantive US Healthcare LLC has requested revocation of the EUA for the Prismaflex ST Sets, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200704 for the Prismaflex ST Sets pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Prismaflex ST Sets is no longer authorized for emergency use by FDA.

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

Sincerely,

ELLEN J. FLANNERY -S

Digitally signed by ELLEN J. FLANNERY -S
Date: 2026.08.10 10:23:15 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration