December 2, 2022

Beth Lingenfelter
VP of Clinical and Regulatory Affairs
Visby Medical, Inc.
3010 North First Street
San Jose, CA 95134

Re: Revocation of EUA202677

Dear Ms. Lingenfelter:

This letter is in response to the request from Visby Medical, Inc., received via email on November 29, 2022, that the U.S. Food and Drug Administration (FDA) close the EUA for the Visby Medical COVID-19 issued on September 16, 2020, amended on December 28, 2020, and reissued on August 31, 2021. Visby Medical, Inc. discontinued manufacturing the Visby Medical COVID-19 test on January 25, 2021, and FDA understands there are no viable (non-expired) Visby Medical COVID-19 tests remaining in distribution in the United States.

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 Visby Medical, Inc. has requested FDA close the EUA for the Visby Medical COVID-19, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202677 for the Visby Medical COVID-19, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Visby Medical COVID-19 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,

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Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration