June 30, 2021

Mr. Yasser Estafanous
Director for Regulatory Affairs and Quality Assurance
3B Medical, Inc.
203 Avenue A NW, Suite 300
Winter Haven, FL 33881

Re: Revocation of EUA

Dear Mr. Estafanous:

This letter is in response to 3B Medical, Inc.'s (3B Medical's) request dated June 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Lumin LM3000 Bioburden Reduction UV System (hereafter referred to as "3B Medical Bioburden Reduction System") issued on December 3, 2020. 3B Medical will no longer make the 3B Medical Bioburden Reduction System available for the authorized emergency use. In its request, 3B Medical confirmed that it has ceased operation of all 3B Medical Bioburden Reduction 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 3B Medical 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 3B Medical's EUA for the 3B Medical Bioburden Reduction System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the 3B Medical Bioburden Reduction System is no longer authorized for emergency use by FDA.

FDA encourages 3B Medical 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