March 9, 2023

Sue Werner
Head of Regulatory Affairs
Biocartis US, Inc.
Two Pierce Place, Suite 1510
Itasca, IL 60143

Re: Revocation of EUA160008

Dear Sue Werner:

This letter is in response to the request from Biocartis US, Inc., on behalf of Biocartis NV, in a letter received November 23, 2022, that the U.S. Food and Drug Administration (FDA) rescind the EUA for the Idylla Rapid Ebola Virus Triage Test issued on May 26, 2016. Biocartis US, Inc. indicated that Biocartis has discontinued production of the authorized product, has no plans to re-initiate production, and has requested that the EUA be rescinded. FDA understands that no Idylla Rapid Ebola Virus Triage Test reagents associated with this EUA are being produced or are available to the United States market.

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 Biocartis US, Inc. has requested FDA rescind the EUA for the Idylla Rapid Ebola Virus Triage Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA160008 for the Idylla Rapid Ebola Virus Triage Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Idylla Rapid Ebola Virus Triage Test 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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration