March 30, 2023

Riva Dill-Garlow
Regulatory Affairs Specialist III
Cepheid
904 Caribbean Drive,
Sunnyvale, CA 94089

Re: EUA220483/S001
Trade/Device Name: Xpert Mpox
Dated: February 28, 2023
Received: February 28, 2023

Dear Ms. Dill-Garlow:

This is to notify you that your request to update the Xpert Mpox Emergency Use Authorization to include information concerning: (1) registration and listing consistent with 21 CFR Part 807, provided to fulfil Condition of Authorization J; (2) the current list of authorized distributors, provided to fulfil Condition of Authorization K; and (3) Cepheid's current quality system, provided to fulfill Condition of Authorization W listed in the February 10, 2023, Letter of Authorization, is granted. Upon review, we concur that the information submitted in EUA220459/S001 fulfills Conditions of Authorization J, K and W listed in the February 10, 2023, letter. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Xpert Mpox issued on February 10, 2023.

Sincerely yours,

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Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health