December 23, 2020

Irma Barr,
Principal Regulatory Affairs Specialist
Cepheid
904 Caribbean Drive,
Sunnyvale, CA 94089

Re: EUA202699/S001
Trade/Device Name: Xpert Omni SARS-CoV-2
Dated: December 11, 2020
Received: December 21, 2020

Dear Irma Barr:

This is to notify you that your request to update the GeneXpert Omni System product labels to include the CE Mark is granted. By submitting these revisions 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 Omni SARS-CoV-2 issued on November 27, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
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