November 4, 2022

Sweta Srivastava
Manager, Regulatory Affairs
Thermo Fisher Scientific, Inc.
5781 Van Allen Way
Carlsbad, CA 92008

Re: EUA210257/S004
Trade/Device Name: Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit
Dated: September 12, 2022
Received: September 12, 2022

Dear Ms. Srivastava:

This is to notify you that your request to; (1) extend reagent shelf-life claims for various reagents used in the Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit, including components in the TaqPath COVID-19 High-Throughput Combo Kit and the Amplitude High-Throughput Consumable Package 1 Reagent Kit, (2) revise the IFU with updates made to the hardware and software for the Amplitude Solution V2.2, and (3) revise the IFU with additional minor clarifying and formatting edits, is granted. Upon review, we concur that the data and information submitted in EUA210257/S004 supports the requested updates for use with the Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit. 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 reissued letter authorizing the emergency use of the Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit issued on October 12, 2021.

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