October 17, 2020

Brian Yang
Chief Executive Officer
Beijing Tongze Medical Technology Co. Ltd.
Representing: Biohit Healthcare (Hefei) Co. Ltd.
Suite 0617, 6th Floor, Building 1 Guoyingyuan
Xicheng District
Beijing, 100035 China

Re: EUA200192/S002
Trade/Device Name: Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit
Dated: August 14, 2020
Received: August 14, 2020

Dear Mr. Yang:

This is to notify you that your request pertaining to revise the distribution list for one additional authorized distributor, ThermoGenesis Holdings Inc. to market the Biohit Healthcare (Hefei) Co. Ltd.'s EUA authorized Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit (EUA200192) under the device name of ThermoGenesis SARS-CoV-2 IgM/IgG Antibody Test Kit is granted. Further, the extension of your expiration dates of the device up to 6 months and controls up to 5 months is also granted. The protocol for the validation of the new manufacturing facility provided by email on October 5, 2020 was found to be acceptable. Upon review, we concur that the data and information submitted in EUA200192/S002 and subsequent interactive review supports the requested updates for use with the Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit. 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 Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit issued on June 18, 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