April 5, 2022

Katie Edwards, M.Sc., RAC
Director, Regulatory Affairs
Biomeme, Inc.
401 N Broad Street Suite 222,
Philadelphia, PA 19108

Re: EUA201209/S001, S006 and S007
Trade/Device Name: Biomeme SARS-CoV-2 Real-Time RT-PCR Test
Dated: September 30, 2020, December 22, 2021, and January 18, 2022
Received: September 30, 2020, December 24, 2021, and January 19, 2022

Dear Katie Edwards:

This is to notify you that your request to; (1) update the authorized labeling to address Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, (2) update the in-use stability of the RNA Process Control (RPC) kits once resuspended, (3) include use of the Biomeme Go Dx App mobile application for use with the Biomeme Franklin three9 Real-Time PCR Thermocycler, and (4) add use of the KingFisher Flex Purification System when used with the KingFisher with 96 PCR head and the MagMAX Viral/Pathogen Nucleic Acid Isolation Kit as an authorized extraction method, is granted. Upon review, we concur that the information submitted in EUA200667/S001, S006 and S007 and subsequent interactive review supports the requested updates for use with the Biomeme SARS-CoV-2 Real-Time RT-PCR Test. FDA have updated the Fact Sheet for Healthcare Providers and Fact Sheet for Patients according to the requested updates and also to reflect more recent authorizations.

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 Biomeme SARS-CoV-2 Real-Time RT-PCR Test issued on August 11, 2020, and the Viral Mutation Revision Letter issued on September 23, 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