August 24, 2022

Jeff Chapman
President and Chief Executive Officer
MicroGEM U.S., Inc.
705D – Dale Avenue
Charlottesville, VA 22903

Re: EUA220216/S002
Trade/Device Name: MicroGEM Sal6830 SARS-CoV-2 Saliva Test
Dated: June 10, 2022
Received: June 10, 2022

Dear Mr. Chapman:

This is to notify you that your request to update the Instructions for Use (IFU), Quick Reference Instructions (QRI) and product labels of the MicroGEM Sal6830 SARS-CoV-2 Saliva Test to reflect the revised packaging format of one test kit box containing 30 individual tests, one Quick Reference Instruction (QRI), one Product Information Card (PIC) and an Intended Use Statement (printed on the test kit box), is granted. Upon review, we concur that the information submitted in EUA220216/S002 supports the requested updates for use with the MicroGEM Sal6830 SARS-CoV-2 Saliva Test. 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 MicroGEM Sal6830 SARS-CoV-2 Saliva Test issued on April 14, 2022.

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