U.S. FOOD & DRUG ADMINISTRATION

April 27, 2021

Michael Campbell
Head of Regulatory Affairs and Quality
Quotient Suisse SA
Business Park Terre Bonne
Route de Crassier 13
1262 Eysins, Switzerland

Re: EUA201083/S001
Trade/Device Name: MosaiQ COVID-19 Antibody Magazine
Dated: October 23, 2020
Received: October 23, 2020

Dear Michael Campbell:

This is to notify you that your request to update the Instructions for Use (IFU) of the MosaiQ COVID-19 Antibody Magazine (EUA201083/S001) to (1) update the software related to signal determination and quality control, (2) to modify the reagent stability to 10 weeks at 15-25°C and on-board reagent stability as up to 96 hours in compliance with condition P of the letter of authorization, and (3) add MosaiQ COVID-19 Antibody Q-Controls external controls is granted. FDA has included minor updates to the intended use and updated the Healthcare Provider and Recipient Fact Sheets 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 MosaiQ COVID-19 Antibody Magazine issued on September 25, 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