

April 27, 2021

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

Re: EUA201083/S0

Trade/Device None: Mg AQ Co XID-19 Antibody Magazine

Dated: October 3, 20 Received: October 2, 2020

Dear Michael Campbell:

This is to notify you that your request, upd the Instructions for Use (IFU) of the MosaiQ COVID-19 Antibody Magazine (EUA201083/S0 , to (1) upd ftware related to signal determination and to 10 week quality control, (2) to modify the reagent stabilit at 15-25°C and on-board reagent stability as up to 96 hours in compliance with condition P the letter of uthorization, and (3) add MosaiQ COVID-19 Antibody Q-Controls external controls is gratted. FDA h included minor updates to the intended use and updated the Healthcare Provider and Recipited Fact Structs to eflect more recent authorizations. By submitting these revisions for review by the Food and Jug A Anistration (FDA), you have complied with the Conditions of Authorization stated in the letter aut the emergency use of the MosaiQ COVID-19 Antibody Magazine issued on September 25, 320.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.

Director, Division of Microbiology De

OHT7: Office of In Vitro Diagnostics and Radiological Health

Office of Product Evaluation and Quality Center for Devices and Radiological Health