January 11, 2022

Michael Campbell
Head of Regulatory Affairs & Quality
Quotient Suisse SA
Route de Crassier 13
Eysins, VD 1262
Switzerland

Re: Revocation of EUA201083

Dear Michael Campbell:

This letter is in response to a request from Quotient Suisse SA, received December 22, 2021, that the U.S. Food and Drug Administration (FDA) terminate the MosaiQ COVID-19 Antibody Magazine – EUA201083 issued on September 25, 2020 and amended April 27, 2021 and September 23, 2021. Quotient Suisse SA decided not to continue to commercially support the MosaiQ COVID-19 Antibody Magazine.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Quotient Suisse SA has notified FDA that Quotient Suisse SA has decided not to continue to commercially support the product and requested FDA terminate the MosaiQ COVID-19 Antibody Magazine – EUA201083, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201083 for the MosaiQ COVID-19 Antibody Magazine, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the MosaiQ COVID-19 Antibody Magazine is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration