April 28, 2022

Kelli Turner
Senior Program Manager
Roche Diagnostics
Representing SD Biosensor, Inc.
C-4th & 5th, 16, Deogyeong-Daero,
1556beon-Gil, Yeongtong-Gu,
Suwon-si, Gyeonggi-Do,
Republic of Korea 16690

Re: EUA210661/S005
Trade/Device Name: Pilot COVID-19 At-Home Test
Dated: March 31, 2022
Received: March 31, 2022

Dear Kelli Turner:

This is to notify you that your request to update the Pilot COVID-19 At-Home Test Healthcare Provider Instructions for Use and the Pilot COVID-19 At-Home Test Quick Reference Instructions for Patients with the results of your post authorization clinical evaluation study to further evaluate your product in pediatric individuals <14 years of age, performed to fulfill Condition of Authorization X. in the April 4, 2022 letter, is granted. Upon review, we concur that the data and information submitted in EUA210661/S005 support the requested update for the COVID-19 At-Home Test and fulfills the Condition of Authorization X. of the April 4, 2022 letter. 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 COVID-19 At-Home Test re-issued on April 4, 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

cc: SunYoung Jeong, SD Biosensor, Inc.