



September 12, 2024

Naeun Lee  
SD Biosensor, Inc.  
C-4th & 5th, 16, Deogyong-Daero  
1556beon-Gil, Yeongtong-Gu  
Suwon-Si, Gyeonggi-Do  
Republic of Korea 16690

Re: EUA220410/S002  
Trade/Device Name: STANDARD Q COVID-19 Ag Test 2.0  
Dated: June 20, 2024  
Received: June 20, 2024

Dear Naeun Lee:

This is to notify you that your request is granted to; (1) update the STANDARD Q COVID-19 Ag Test 2.0 to extend the shelf-life expiration date to 24 months when stored at 2°C – 30°C, (2) update the STANDARD SARS CoV 2 Antigen Control to extend the shelf-life expiration date to 22 months when stored at 2°C – 30°C, based on the results of your stability studies, and (3) include a "Important Product Information for U.S. customers" insert in each shipped box that includes distributor specific U.S. customer service information. Upon review, we concur that the data and information submitted in EUA220410/S002 supports the requested update for the STANDARD Q COVID-19 Ag Test 2.0. 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 STANDARD Q COVID-19 Ag Test 2.0 issued on September 29, 2023.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.  
Director, Division of Microbiology Devices  
OHT7: Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health