



May 1, 2024

Young-Gyun KIM
SD Biosensor, Inc.
C-4th & 5th, 16, Deogyong-Daero,
1556beon-Gil, Yeongtong-Gu,
Suwon-si, Gyeonggi-Do,
Republic of Korea 16690

Re: EUA220410/S001
Trade/Device Name: STANDARD Q COVID-19 Ag Test 2.0
Dated: December 21, 2023
Received: December 21, 2023

Dear Young-Gyun KIM:

This is to notify you that your request to update the STANDARD Q COVID-19 Ag Test 2.0 with data evaluating the precision of the product to fulfill Condition of Authorization U of the September 29, 2023, Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA220410/S001 supports the requested update for the STANDARD Q COVID-19 Ag Test 2.0 and fulfills Condition of Authorization U of the September 29, 2023, 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 STANDARD Q COVID-19 Ag Test 2.0 issued on September 29, 2023.

Sincerely yours,

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