March 30, 2023

Young-Gyun Kim
Regulatory Affairs Manager
SD BIOSENSOR, Inc.
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Re: EUA200140/S003
Trade/Device Name: STANDARD M nCoV Real-Time Detection Kit
Dated: July 12, 2021
Received: July 12, 2021

Dear Young-Gyun Kim:

This is to notify you that your request is granted to update the Instructions for Use (IFU) of the STANDARD M nCoV Real-Time Detection Kit to; (1) update the clinical performance with the results of testing natural clinical specimens, (2) update the inclusivity performance with more recent wet-testing and *in silico* analysis, (3) include minor updates to the intended use to align the language with more recent authorizations and clarify "nasal" as "anterior nasal" specimens, (4) remove use of the LightCycler 480 PCR instrument, (5) include various other minor updates to align the language with more recent authorizations, and (6) in response to Condition of Authorization (1) of the Viral Mutation Revision Letter dated September 23, 2021. Upon review, we concur that the data and information submitted in EUA200140/S003 supports the requested updates for use with the STANDARD M nCoV Real-Time Detection Kit and fulfills Condition of Authorization (1) of the Viral Mutation Revision Letter dated September 23, 2021. FDA have also updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations.

By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Viral Mutation Revision Letter dated September 23, 2021 and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the STANDARD M nCoV Real-Time Detection Kit issued on April 23, 2020.

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