July 2, 2024

Kaiyu Xiao
Regulatory Affairs Manager
Wondfo USA Co., Ltd.
6720 Cobra Way
San Diego, CA, 92121

Re: EUA240011/S002
Trade/Device Name: WELLlife COVID-19 / Influenza A&B Home Test
Dated: June 27, 2024
Received: June 28, 2024

Dear Kaiyu Xiao:

This is to notify you that your request to update the WELLlife COVID-19 / Influenza A&B Home Test with data evaluating additional inclusivity of the product to fulfill Condition of Authorization U. of the April 30, 2024, Letter of Authorization, and data evaluating additional cross reactivity, is granted. Upon review, we concur that the data and information submitted in EUA240011/S002 supports the requested update for the WELLlife COVID-19 / Influenza A&B Home Test and fulfills Condition of Authorization U. of the April 30, 2024, 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 WELLlife COVID-19 / Influenza A&B Home Test issued on April 30, 2024.

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