July 2, 2024

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

Re: EUA240004/S001
Trade/Device Name: WELLlife COVID-19 / Influenza A&B Test
Dated: June 20, 2024
Received: June 20, 2024

Dear Kaiyu Xiao:

This is to notify you that your request to update the WELLlife COVID-19 / Influenza A&B Test with data evaluating additional inclusivity of the product to fulfill Condition of Authorization S. of the April 19, 2024, Letter of Authorization, and data evaluating additional cross reactivity, is granted. Upon review, we concur that the data and information submitted in EUA240004/S001 supports the requested update for the WELLlife COVID-19 / Influenza A&B Test and fulfills Condition of Authorization S. of the April 19, 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 Test issued on April 19, 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