May 21, 2024

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

Re: EUA240011/S001
Trade/Device Name: WELLlife COVID-19 / Influenza A&B Home Test
Dated: May 9, 2024
Received: May 9, 2024

Dear Kaiyu Xiao:

This is to notify you that your request to update the WELLlife COVID-19 / Influenza A&B Home Test to add four new box labels for 1, 5, 10 and 25 Test(s)/kit configurations in addition to the previously authorized 2 Tests/kit option and the associated updates to the WELLlife COVID-19 / Influenza A&B Home Test Healthcare Provider Instructions for Use, is granted. We also concur with the minor updates made to the WELLlife COVID-19 / Influenza A&B Home Test Healthcare Provider Instructions for Use to fix minor typographical errors. Upon review, we concur that the information submitted in EUA240011/S001 supports the requested update for the WELLlife COVID-19 / Influenza A&B Home Test. 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,

Uwe Scherf -S

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