August 19, 2022

Lisa Baumhardt, MS, MJ, MT (ASCP), RAC, FRAPS
Senior Medical Device Regulatory Expert
Hyman, Phelps & McNamara, P.C.
Representing: OSANG LLC
North American Headquarters
177 E. Colorado Blvd. Suite 200
Pasadena, California 91105

Re: EUA220037/S003
Trade/Device Name: OHC COVID-19 Antigen Self Test
Dated: June 2, 2022
Received: June 2, 2022

Dear Lisa Baumhardt:

This is to notify you that your request to update the OHC COVID-19 Antigen Self Test to (1) extend the shelf-life expiration date to 12 months when stored at 2°C – 30°C, based on the results of your ongoing stability studies, (2) offer the OHC COVID-19 Antigen Self Test under the brand name/trade name of QuickFinder COVID-19 Antigen Self Test, (3) add authorized distributors for the QuickFinder COVID-19 Antigen Self Test, and (4) add a QR code to the test cassette, is granted. Upon review, we concur that the data, information, and labeling for QuickFinder COVID-19 Antigen Self Test submitted in EUA220037/S003 are consistent with, and support, the requested updates. 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 OHC COVID-19 Antigen Self Test issued on April 6, 2022.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

cc: Seungyeob Lee (Dan Lee), OSANG LLC