



September 26, 2023

Lisa Baumhardt, MS, MJ, MT (ASCP), RAC, FRAPS
Senior Medical Device Regulatory Expert
Hyman, Phelps & McNamara, P.C.
Representing:
OSANG LLC
215 N. Marengo Ave., 3rd Floor
Pasadena, CA 91101

Re: EUA220037/S010
Trade/Device Name: OHC COVID-19 Antigen Self Test
Dated: September 7, 2023
Received: September 7, 2023

Dear Lisa Baumhardt:

This is to notify you that your request to update the OHC COVID-19 Antigen Self Test to extend the shelf-life expiration date to 24 months when stored at 2°C – 30°C, based on the results of your stability studies, is granted. In addition, we concur with the minor updates to the authorized labeling for the OHC COVID-19 Antigen Self Test and the brand name/trade QuickFinder COVID-19 Antigen Self Test made to (1) fix some typographical errors, (2) update formatting, and (3) include the contact address for OSANG LLC. Upon review, we concur that the data and information submitted in EUA220037/S008 support the requested updates for the OHC COVID-19 Antigen Self Test and the brand name/trade QuickFinder COVID-19 Antigen Self 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 OHC COVID-19 Antigen Self Test issued on April 6, 2022.

Sincerely yours,

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