May 21, 2024

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: EUA230042/S001
Trade/Device Name: OHC COVID-19/Flu Antigen Test Pro
Dated: April 18, 2024
Received: April 18, 2024

Dear Lisa Baumhardt:

This is to notify you that your request to update the OHC COVID-19/Flu Antigen Test Pro with data evaluating additional inclusivity of the product to fulfill Condition of Authorization T of the March 21, 2024, Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA220410/S001 supports the requested update for the OHC COVID-19/Flu Antigen Test Pro and fulfills Condition of Authorization T of the March 21, 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 OHC COVID-19/Flu Antigen Test Pro issued on March 21, 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