U.S. FOOD & DRUG ADMINISTRATION

September 4, 2024

Dimitris Demirtzoglou
Director, Regulatory Affairs
SEKISUI Diagnostics, LLC
One Wall Street
Burlington, MA 01803

Re: EUA240002/S001 & S002
Trade/Device Name: OSOM Flu SARS-CoV-2 Combo Home Test
Dated: May 14, 2024 & July 26, 2024
Received: May 15, 2024 & July 26, 2024

Dear Dimitris Demirtzoglou:

This is to notify you that your request is granted to update the OSOM Flu SARS-CoV-2 Combo Home Test with; (1) data evaluating additional inclusivity of the product to fulfill Condition of Authorization U. of the February 29, 2024, Letter of Authorization, (2) data evaluating the WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368), and (3) data to extend the shelf-life expiration date to 12 months when stored at 15°C – 30°C, based on the results of your stability studies. Upon review, we concur that the data and information submitted in EUA240002/S001 & S002 supports the requested update for the OSOM Flu SARS-CoV-2 Combo Home Test and fulfills Condition of Authorization U. of the February 29, 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 OSOM Flu SARS-CoV-2 Combo Home Test issued on February 29, 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