May 14, 2024

Dennis Shay, Ph.D.
Director of Regulatory Affairs
3EO Health, Inc.
48 Dunham Ridge Road
Suite 4350
Beverly, MA 01915

Re: EUA230035/S002
Trade/Device Name: 3EO Health COVID-19 Test
Dated: January 26, 2024
Received: January 26, 2024

Dear Dr. Shay:

This is to notify you that your request to provide a report of investigations and corrective and preventative actions for both the underfill and bubble issues in the 3EO Key within the 3EO Health COVID-19 Test, to fulfill Condition "T." of the September 19, 2023, Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA230035/S002 supports the requested updates for use with the 3EO Health COVID-19 Test and fulfills Condition of Authorization "T." from the September 19, 2023, Letter of Authorization. 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 3EO Health COVID-19 Test issued on September 19, 2023.

Sincerely yours,

For

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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