December 22, 2022

Hairong Zhang
Xiamen Boson Biotech Co., Ltd
90-94 Tianfeng Road,
Jimei North Industrial Park,
Xiamen, Fujian 361021, China

Re: EUA220120/S007 & S008
Trade/Device Name: Rapid SARS-CoV-2 Antigen Test Card
Dated: October 5, 2022 and November 17, 2022
Received: October 5, 2022 and November 17, 2022

Dear Hairong Zhang:

This is to notify you that your request to update authorized labeling of the Rapid SARS-CoV-2 Antigen Test Card; (1) include details of your optional web-based reporting application developed to address Condition of Authorization S. in the April 6, 2022 Letter of Authorization, and (2) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A of the letter, and make various updates to the authorized labeling as required and described in Appendix B of the letter, is granted. Upon review, we concur that the data and information submitted in EUA220120/S007 & S008 supports the requested updates for use with the Rapid SARS-CoV-2 Antigen Test Card and fulfills Condition of Authorization S. from the April 6, 2022, letter and Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Professionals has been updated by FDA consistent with this revision and is included along with this letter.

By submitting these supplemental requests for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Rapid SARS-CoV-2 Antigen Test Card issued on April 6, 2022.

Sincerely yours,

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Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health