July 22, 2020

Mari Meyer
Vice President, Regulatory and Clinical Affairs, North America
DiaSorin Inc.
1951 Northwestern Ave.
Stillwater, MN 55082

Re: EUA200404/S001
Trade/Device Name: LIAISON SARS-CoV-2 S1/S2 IgG
Dated: July 10, 2020
Received: July 10, 2020

Dear Ms. Meyer:

This is to notify you that your request to update the Instructions for Use (IFU) of the LIAISON SARS-CoV-2 S1/S2 IgG to; (1) extend the in use reagent integral for the test calibration curve from one week to two weeks, (2) extend the open reagent integral when stored at 2-8°C from one week to two weeks, (3) extend the open reagent integral when stored on-board the LIAISON XL analyzer from one week to two weeks for the LIASON SARS-CoV-2 S1/S2 IgG assay, and (4) make some additional minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200404/S001 supports the extension to two weeks for the test calibration and the stability of the open reagent integral for the LIASON SARS-CoV-2 S1/S2 IgG assay. By submitting this amendment 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 LIASON SARS-CoV-2 S1/S2 IgG assay issued on April 24, 2020.

Sincerely yours,

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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