October 19, 2020

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

Re: EUA200404/S003
Device Name (Authorized): LIAISON SARS-CoV-2 S1/S2 IgG assay
Authorization Date: April 24, 2020
Supplement Received: September 24, 2020

Dear Ms. Mari Meyer:

This is to notify you that your request to update the Fact Sheet for Healthcare Providers and the Instructions for Use (IFU) of the LIAISON SARS-CoV-2 S1/S2 IgG assay, to include a limitation, is granted. Upon review, for the LIAISON SARS-CoV-2 S1/S2 IgG assay, we concur with the additional limitation to the package insert: "*A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.*" We also concur with the additional statement to the Fact Sheet for Health Care Providers: "*Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies.*" for the LIAISON SARS-CoV-2 S1/S2 IgG assay. FDA also made minor updates to the IFU, the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to reflect more recent authorizations.

By submitting this 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 LIAISON SARS-CoV-2 S1/S2 IgG assay issued on April 24, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
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