U.S. FOOD & DRUG ADMINISTRATION

February 16, 2022

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

Re: EUA202960/S002
Trade/Device Name: LIAISON SARS-CoV-2 Ag
Dated: July 20, 2021
Received: July 21, 2021

Dear Mari Meyer:

This is to notify you that your request to update the Instructions for Use (IFU) of the LIAISON SARS-CoV-2 Ag to include; (1) the results of the post authorization prospective clinical evaluation performed to fulfill Condition of Authorization R. from the March 26, 2021 letter of authorization, and (2) other minor updates and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA202029/S002 supports the requested updates for use with the LIAISON SARS-CoV-2 Ag. FDA have also updated the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to be consistent with more recent authorizations. 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 LIAISON SARS-CoV-2 Ag issued on March 26, 2021.

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