December 17, 2021

Christoffer Riska
Vice President Regulatory Affairs, Quality Assurance
Salofa Oy
Örninkatu 15
Salo, Finland 24100

Re: EUA210062/S001
Trade/Device Name: Sienna-Clarity COVID-19 Antigen Rapid Test Cassette
Dated: June 7, 2021
Received: June 7, 2021

Dear Mr. Riska:

This is to notify you that your request to add additional authorized distributors of the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (EUA210062) to be distributed under the brand names (1) Sienna COVID-19 Antigen Rapid Test Cassette, (2) Clarity COVID-19 Antigen Rapid Test Cassette, (3) OVIOS COVID-19 Antigen Rapid Test Cassette, (4) Spring Health COVID-19 Antigen Rapid Test, and (5) Salocor COVID-19 Antigen Rapid Test Cassette, is granted. Upon review, we concur that the information submitted in EUA210062/S001 supports the requested updates for the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette. FDA also made minor updates to the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect 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 Sienna-Clarity COVID-19 Antigen Rapid Test Cassette issued on May 20, 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

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