October 25, 2022

Bryan Bothwell,
Sr. Director of Strategy and Business Development
Qorvo Biotechnologies, LLC.
14505 21st Ave N., Suite 212
Plymouth, MN 55447

Re: EUA203121/S002
Trade/Device Name: Omnia SARS-CoV-2 Antigen Test
Dated: September 19, 2022
Received: September 19, 2022

Dear Bryan Bothwell:

This is to notify you that your request to update the contact website listed in the Fact Sheet for Healthcare Providers and the Qorvo Biotechnologies Omnia System instrument label to https://www.qorvobiotech.com/support/, is granted. Upon review, we concur that the information submitted in EUA203121/S002 supports the requested updates for use with the Omnia SARS-CoV-2 Antigen Test. 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 Omnia SARS-CoV-2 Antigen Test reissued on July 29, 2022.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Cc: Joanne Lebrun, Vice President, MDC Associates, Inc., Representing Qorvo Biotechnologies, LLC.