



November 2, 2021

Meijie Tang, Ph.D.
Chief Executive Officer & President
Nirmidas Biotech, Inc.
2458 Embarcadero Way
Palo Alto, CA 94303

Re: EUA202743/S008
Trade/Device Name: MidaSpot COVID-19 Antibody Combo Detection Kit
Dated: October 5, 2021
Received: October 6, 2021

Dear Meijie Tang:

This is to notify you that your request to extend the MidaSpot COVID-19 Antibody Combo Detection Kit shelf-life stability claim to 12 months when stored at 4-25°C is granted. Upon review, we concur that the data and information submitted in EUA202743/S008 support the requested updates for use with the MidaSpot COVID-19 Antibody Combo Detection Kit. By submitting this information 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 MidaSpot COVID-19 Antibody Combo Detection Kit issued on December 31, 2020.

Sincerely yours,

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