



July 14, 2022

Colton Muraira, J.D.
Staff Regulatory Affairs Specialist
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: EUA200159/S008
Trade/Device Name: BD SARS-CoV-2 Reagents for BD MAX System
Dated: June 30, 2022
Received: June 30, 2022

Dear Colton Muraira:

This is to notify you that your request to update the title and content of the “BD SARS-CoV-2 Reagents for BD MAX System / BD SARS-CoV-2/Flu for BD MAX System” flyer to be specific for the BD SARS-CoV-2 Reagents for BD MAX System, is granted. Upon review, we concur that the updated “BD SARS-CoV-2 Reagents for BD MAX System” flyer and information submitted in EUA200159/S008 supports the requested updates for use with the BD SARS-CoV-2 Reagents for BD MAX System. 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 BD SARS-CoV-2 Reagents for BD MAX System re-issued on February 14, 2022.

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