U.S. FOOD & DRUG ADMINISTRATION

April 9, 2021

Kristen Bankert, Ph.D.
BD Integrated Diagnostics Solution Division
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: EUA202975/S001 & S002
Trade/Device Name: BD SARS-CoV-2/Flu for BD MAX System
Dated: February 19, 2021 and March 10, 2021
Received: February 19, 2021 and March 10, 2021

Dear Dr. Bankert:

This is to notify you that your request to update the Instructions for Use (IFU) of the BD SARS-CoV-2/Flu for BD MAX System to; (1) include use of anterior nasal swab specimens collected and stored in saline, (2) include results of the FDA SARS-CoV-2 Reference Panel (reviewed under EUA202975/S002) and (3) make some clarifications to Table 6, is granted. Upon review, we concur that the data and information submitted in EUA202975/S001 & S002 supports the requested updates for use with the BD SARS-CoV-2/Flu for BD MAX System. FDA also concurs with updates made to the product information sheet (flyer) that is included with each shipped product. In addition, FDA has updated the Fact Sheet for Healthcare Providers and 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 BD SARS-CoV-2/Flu for BD MAX System issued on February 10, 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

REVOKED

U.S. Food & Drug Administration
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