



December 29, 2020

Xu Jiafa
Jiangsu Biopertectus Technologies Co., Ltd.
Taizhou National Medical, Hi-tech Development Zone
Taizhou, Jiangsu, CHN 225300

Re: EUA201047/S001
Trade/Device Name: COVID-19 Coronavirus Real Time PCR Kit
Dated: December 13, 2020
Received: December 16, 2020

Dear Xu Jiafa:

This is to notify you that your request to update the product labels, Instructions for Use (IFU) and Fact Sheet for Healthcare Providers of the COVID-19 Coronavirus Real Time PCR Kit to include updated contact and website information, is granted. FDA made updates to the IFU to reflect more recent authorizations and reporting requirements for SARS-CoV-2. FDA also updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect more recent authorizations. By submitting these revisions 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 COVID-19 Coronavirus Real Time PCR Kit issued on June 18, 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