December 9, 2020

Canan Ketre Kolukirik, M.Sc.
Bioeksen R&D Technologies Ltd.
Rresitpasa MH Katar CD. Teknokent,
ARI 3 No:4 B105
Instanbul, TUR 34469

Re: EUA200488/S002
Trade/Device Name: Bio-Speedy Direct RT-qPCR SARS-CoV-2
Dated: November 10, 2020
Received: November 10, 2020

Dear Canan Ketre Kolukirik:

This is to notify you that your request to revise the distribution list to add one additional authorized distributor, BioeXsen GmbH, to market the Bioeksen R&D Technologies Ltd.'s EUA authorized Bio-Speedy Direct RT-qPCR SARS-CoV-2 under the device brand name of BioeXsen SARS-CoV-2 RT PCR is granted. By submitting this 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 Bio-Speedy Direct RT-qPCR SARS-CoV-2 issued on September 2, 2020.

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