



Acknowledgment Letter

2/16/2021

Nickita Alexiades
mdi Consultants, Inc.
55 Northern Boulevard Suite 200
Great Neck, NY 11021
UNITED STATES

Dear Nickita Alexiades:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA210149

Received: 2/13/2021

Applicant: Unioninvest Gida Tur. San. Dis Tic. Ltd. Sti.

Device: Unibioscience COVID-19 Rapid Antigen Test

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health