"DECLARATION OF CONFORMITY "

Manufacturer:	ProGnosis Biotech SA
Business Address:	Farsalon 153, 41335, Larissa, Greece
In Vitro Medical device designation:	Rapid Test Ag 2019 n-Cov
Catalogue no:	V1301/V1302/V1304/V1310/V1320/V1330/V1340
GIVD code:	15.70.90.90 (Other Virology RT & POC)
Classification:	Other device, Self Declaration IVD-MD
Conformity assessment route:	In vitro diagnostic medical device self-certification (not included in list A or B of Annex II of the Directive 98/79/EC), Annex III Applied (IVDD 98/79/EC)

We hereby declare under our sole responsibility that the above In Vitro medical device is manufactured according to certified ISO 13485: 2016 Quality Management System, and conforms with the essentials requirements listed in the Annex I of the European in vitro Medical Device Directive 98/79/ EC (IVD)

Authorized Signatory

"PROGNOSIS BIOTECH"
PROGNOSIS BIOTECH ΑΝΩΝΥΜΗ ΕΤΑΙΡΙΑ
ΠΑΡΑΓΩΓΗ ΧΗΜΙΚΩΝ ΠΡΟΪΟΝΤΩΝ
ΦΑΡΣΑΛΩΝ 153 - ΛΑΡΙΣΑ - Τ.Κ. 41335
Α.Φ.Μ. 997845150 - ΔΟΥ ΛΑΡΙΣΑΣ
ΑΡ. ΓΕΜΗ: 116245240000

Georgios Papageorgiou, Co Founder

Date

30/06/2021