# "DECLARATION OF CE CONFORMITY"

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|---|---|
| **Manufacturer:** | ProGnosis Biotech SA |
| **Business address** | Farsalon 153, 41335 Larissa, Greece |
| **In Vitro Medical device designation** | Rapid Test Ag 2019-nCoV, |
| **Catalogue no** | V1310/V1330, |
| **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 essential requirements listed in the Annex I of the European in vitro Medical Device Directive 98/79/EC (IVD).*

**Authorized Signatory** **13/11/2020**

Name, signature, company stamp

"PROGNOSIS BIOTECH"
PROGNOSIS BIOTECH ΑΝΩΝΥΜΗ ΕΤΑΙΡΙΑ
ΠΑΡΑΓΩΓΗ ΧΗΜΙΚΩΝ ΠΡΟΪΟΝΤΩΝ
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ΑΡ. ΓΕΜΗ: 116245240000
ΠΑΠΑΓΕΩΡΓΙΟΥ Κ. ΓΕΩΡΓΙΟΣ

Date