

for In Vitro Diagnostic Medical Devices according to Annex III of the 98/79/EC IVD Directive

BioMaxima S.A., Vetterów 5, 20-277 Lublin, Poland hereby declare under our sole responsibility that the products:

2019-nCOV IgG/IgM Rapid Test (Cat. No 1-363-K025)

classified as "Other IVD Medical Devices (all except listed in List A or List B and devices for self-testing)" according to Article 9 rules, conform to the relevant provisions of the EC Council Directive 98/79/EC and are in accordance with Annex III of the IVDD, as implemented by the European Union's Medical Devices Regulations.

Place and date of issue:

Lublin, 23.04.2020

Signed on behalf of BioMaxima S.A.:

Name: Henryk Lewczuk

Function: Vice President

Name: Patrycja Paniak-Sankowska

Function: Proxy