Part XVI. Declaration of Conformity

DECLARATION OF CONFORMITY

Manufacturer: RapiGEN Inc.
3-4F, 16, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do 14119, Republic of Korea

European Representative: MT Promedt Consulting GmbH
Altenhofstrasse. 80, 66386 St. Ingbert, Germany

CE

Product: BIOCREDIT COVID-19 Ag
Catalog no.: G61RHA20

Classification: Neither listed in the annex II of the IVDD, nor self-testing device
EDMA code: 15 70 90 90 00, Other Other Virology Rapid Tests
Conformity Assessment Route: Self Declaration (according to annex III of IVDD)

We herewith declare that the above mentioned products meet the provisions of the council Directive 98/79EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied :ISO13485:2016, EN ISO14971:2012, EN13640:2002, EN13641:2002, EN13612:2002, EN ISO 15223-1:2016, ISO17511:2003, EN13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 62366:2008

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Place, Date of Issue: Gyeonggi-Do, Republic of Korea, 9th September, 2020.

Signature: Park Jae-Ku

Jae-Ku, Park
CEO/President
RapiGEN Inc.