

# 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



Product : BIOCREDIT COVID-19 Ag

Catalog no.: G61RHA20

Classification: Neither listed in the annex II of the IVDD, nor self-testing device

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

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, KGMP

Place, Date of Issue: Gyeonggi-Do, Republic of Korea, 29<sup>th</sup> July, 2020.

Signature:

A handwritten signature in black ink, appearing to read 'Park Jae-Ku', is written over a light blue rectangular background.

Jae-Ku, Park  
CEO/President  
RapiGEN Inc.