

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 IgG/IgM Combo

Catalog no.: G62RHA25

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

Place, Date of Issue: Gyeonggi-Do, Republic of Korea, 19th August, 2020.

Signature:

Jae-Ku, Park
CEO/President
RapiGEN Inc.

