DECLARATION OF CONFORMITY

MANUFACTURER : GenBody Inc.
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do 31077, Republic of Korea

EUROPEAN REPRESENTATIVE EC REP : MT Promedt Consulting GmbH
Altenhofstr. 80
D-66386 St. Ingbert, Germany

PRODUCT : GenBody COVID-19 IgM/IgG

CATALOG NO. : COVI025, COVI040

EDMA code/ Term : 15 04 80 90 00 Other Viral Antigen/Antibody Detection

CLASSIFICATION : Others
(Neither Listed in Annex II of IVDD, nor self-testing device)

CONFORMITY ASSESSMENT ROUTE : IVDD ANNEX Ⅲ

We here with declare that the above mentioned products meet the provisions of the council directive 98/79/EC for In Vitro diagnostic medical device. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED: IVD directive 98/79/EC, EN ISO 13485:2016, EN ISO 15193:2009, EN13612:2002, EN ISO 23640:2015, EN 14136:2004, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13975:2003, EN ISO 15194:2009, EN 13641:2002, EN 15223-1:2016, EN 62366:2008

PLACE, DATE OF ISSUE : Chungcheongnam-do, Republic of Korea, Mar 02, 2020

SIGNATURE : _____
Chom-Kyu Chong, Ph.D.

CE