

Registered No. 2020 - 2190

NOTARIAL CERTIFICATE

E TECHNOLOGIES

IN MEDICINE

PYEONG-HWA LAW AND NOTARY PUBLIC OFFICE 80-1, EULJI-RO, JUNG-GU, SEOUL, KOREA

TEL: 776-5371, 7680 / FAX: 776-7682

210mm x 297mm(보존용지 (1종) 70g/m²

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 lgM/lgG

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

: IVDD ANNEX III

ASSESSMENT ROUTE



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, 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, Apr 17, 2020

SIGNATURE

Chom-Kyu Chong, Ph.D.

등부 2020년 제 2190 호 Registered No. 2020 - 2190

증

Notarial Certificate

위 적합성선언서 사본은

원본과 대조하여 그와 일치함을 인정한다.

2020년

이 사무소에서 위 인증한다.

공증인가 평화합동법률사무소 서울중앙지방검찰청 소속 서울특별시 중구 을지로 80-1

As a result of checking at my office I have found that the attached

DECLARATION OF CONFORMITY— Copy

exactly corresponds with the original.

This is hereby attested on this 1st day of May, 2020 at this office

PYEONG-HWA LAW AND NOTARY PUBLIC OFFICE Belong to Seoul Central District Prosecutor's Office 80-1, Eulji-Ro, Jung-Gu, Seoul, Korea

Attorney-at-law Lee Sun Hee

This office has been authorized by the Minister of Justice, the Republic of Korea, to act as Notary Public since Sep. 8, 1971 under Law No. 2254