

EC DECLARATION OF CONFORMITY

Doc. Reference No.: DOC-CV9017

Manufacturer: Labgenomics Co., Ltd.
#1204, 12F, 147, Gwanggyo-ro, Yeongtong-gu, Suwon-si,
Gyeonggi-do 26229, Republic of Korea

EC Representative: Obelis S.A.
Bld. Général Wahis 53
1030 Brussels, Belgium

Product Name: LabGun™ COVID-19 Assay

Brand Name: LabGun™

Product Identification No.: CV9017A, CV9017B, CV9017C

Classification: Others (neither listed in Annex II, nor self-testing device)

Conformity Assessment Route: Annex III of the IVDD 98/79/EC

We herewith declare that the above mentioned product meets the provisions of the Council Directive 98/79/EC for In-vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied :

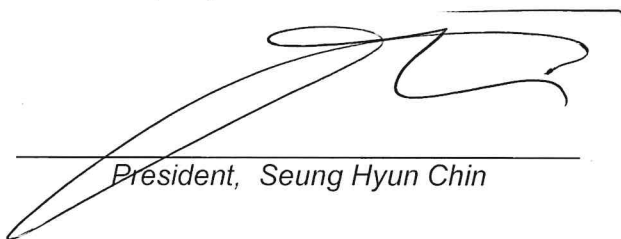
EN ISO 13485:2012, EN ISO 14971:2012,
EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002,
EN 13640:2002, EN ISO 23640:2015, EN ISO 15223-1:2016)

Start of CE-marking: February 21st, 2020

Date of Issue: February 21st, 2020

Place: Suwon, Republic of Korea

Signature:



President, Seung Hyun Chin