Lumigenex

GJ-CE-2020DoC(Ver.02)

Declaration of Conformity

CE

Manufacturer:
Lumigenex (Suzhou) CO., Ltd. Located at building C24, 218 Xing Hu Street, SIP,Suzhou, P.R. China 215123
TEL +86 (512) 80988088 FAX +86 (512) 80988096

European Representative:
Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

Products Name:
PocRoc ® SARS-CoV-2 Antigen Rapid Test Kit（Colloidal Gold）

Product code: P23001, P23005,P23025,P23050.

Classificaiton Under IVDD:
IVDD Other

Conformity assessment route: Annex III
We hereby declare under the sole responsibility of the manufacturer that the product mentioned above meets the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices. All supporting documentations are retained at the premises of the manufacturer.

General applicable directive:
Directive 98/ 79/EC of European Parliament and of the Council of 27 October 1998 on in vitro Diagnostic Medical Devices.

Standards applied:
EN ISO 18113-1:2011, EN ISO 14971:2012, EN ISO 13485:2016,EN ISO 18113-2:2011, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016, EN ISO 17511:2000, EN 13612: 2002

First start of CE-MARC: Nov.1, 2020
Signature:
Mr. Eric Liu (Vice President)

Place, Date of issue: Suzhou, Nov.1, 2020