4. EU-Konformitätserklärung

Declaration of conformity

Hoyotek

Manufacturer: Hoyotek Biomedical Co., Ltd.
Floor 4, Zone C, Workshop No.1, China civil Aviation science and technology industrialization base No. 225, Jinger Road, Tianjin Airport Economic Zone.

European Representative: QAdvis EAR AB
Ideon Science Park
Scheelevägen 17 SE-223 70 Lund, Sweden

Product Name: Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)
Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)
Corona Virus (COVID-19) Combined (IgM/IgG/Neutralizing antibody) Rapid Test (Colloidal Gold)

Product Model: HYT-G01, HYT-G02, HYT-G03

Classification: Other IVD Devices

Conformity assessment Route: IVDD 98/79/EC Annex III

We, Hoyotek Biomedical Co., Ltd hereby declare that the devices mentioned above comply with applicable parts of the Swedish In-Vitro Diagnostic Medical Device Act SFS 1993:584, and the Swedish national legislation LVFS 2001:7, transposing the European In-Vitro Diagnostic Medical Devices Directive, IVDD 98/79/EC.

Verification to: Standard ISO13485:2016, EN ISO14971:2012, EN ISO15223-1:2016, EN ISO18113-1:2011, EN ISO 18113-2:2011, EN ISO18113-3:2011
Related to Directive(s):
98/79/EC (in Vitro Diagnostic Medical Devices)

Approved by:

General Manager : Wu Bo — Tianjin Wu Bo 2020.11.12

Name	**Signature**
Function	**Place and Date of issue**