QAdvis EAR European Authorized Representative

Your Regulatory Partner

Certificate of CE registration

QAD 1056

Manufacturer name and address: 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, China

Product name:	**Model:**
Corona Virus (COVID-19) Antigen Rapid Test (colloidal gold)	HYT-G01
Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test (colloidal gold)	HYT-G02
Corona Virus (COVID-19) Combined (IgM/IgG/Neutralizing antibody) Rapid Test (colloidal gold)	HYT-G03

QAdvis EAR as a European Authorized Representative designated by the manufacturer certifies that the products listed above have been notified and filed at the Competent Authority, Swedish Medical Products Agency, as CE-marked In Vitro Diagnostic Medical Devices in accordance with the In Vitro Diagnostic Medical Devices Directive 98/79/EC, article 10.3.

The manufacturer has provided QAdvis EAR with Declaration of Conformity declaring conformance with the requirements in In Vitro Diagnostic Medical Devices Directive 98/79/EC.

Registration data at Swedish Medical Products Agency:

Reference number: 1607413694862
Initial notification to Swedish Medical Products Agency for the products listed above on 2020-12-08.

Date: 2020-12-08

Bing Wu
EAR manager

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EC REP

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