EC-Declaration of Conformity

Manufacturer:	SINGUWAY BIOTECH INC. B1302, Life Science Park, Shen Cheng Tou Innovation Factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, Guangdong Province, China
Authorized representative:	CMC MEDICAL DEVICES & DRUGS S.L. C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Product:	COVID-19 IgG/IgM Detection Kit(Colloidal gold)
Classification:	Others (IVDD, Article 9)
Conformity Assessment Route:	Annex III of IVDD
Applicable Standards:	EN ISO 13485:2016, EN ISO 14971: 2012,EN ISO 15223-1:2016, EN 13641：2002, EN ISO 23640: 2015,EN 13612:2002/AC: 2002, EN ISO 17511:2003,EN ISO 18113-1:2011, EN ISO 18113-2:2011
EC Certificates:	Not applicable

CE

We herewith declare under our sole responsibility that above mentioned products meets the provisions of the Council Directive 98/79/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer. The mention products bear the CE-Marking according to IVDD 98/79/EEC, and are in compliance with the essential requirements according to annex I of the directive.

The validity with the date of issue.

Signature by:

chen yaqiu

(date, sign General Manager) March 22, 2020

SINGUWAY BIOTECH INC. 深圳市新元微生物科技有限公司 中国 深圳 SHENZHEN CHINA

List of products conc. Declaration of Conformity

Product description	GIVD CODE
COVID-19 IgG/IgM Detection Kit(Colloidal gold)	15.04.80.19