

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: Detection Kit For Coronavirus Disease 2019 (PCR Fluorescence Probe)

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



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 yaqin

(date, sign General Manager) March 22, 2020



List of products conc. Declaration of Conformity

| Product description | GIVD CODE |
|--|-------------|
| Detection Kit For Coronavirus Disease 2019 (PCR Fluorescence Probe) | 15.04.40.90 |
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