

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)

Catalogue number: PCR020

Classification: Others (IVDD, Article 9)
Not in annex II , not for self-testing, not for performance
evaluation

Conformity Assessment Route: Annex III of IVDD

Applicable Standards: EN ISO 13485:2016, EN ISO 14971: 2012,
EN ISO 15223-1:2016, EN 62304:2006/AC: 2008,
EN 62366:2008, IEC 61010-1:2010+A1:2016,
IEC 61010-2-101:2015/EN 61010-2-101-2017,
EN 61010-2-010:2014,
IEC 61326-1:2012/EN 61326-1:2013,
IEC 61326-2-6:2012/EN 61326-2-6:2013,
EN ISO 18113-1:2011, EN ISO 18113-3:2011

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 yagui*
(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