

## 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:** PCR001

**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