



**EC DECLARATION OF CONFORMITY**  
According to the In Vitro Diagnostic Medical Devices Directive  
Annex III of 98/79/EC

**Manufacturer :** Shenzhen Bioeasy Biotechnology Co.,Ltd  
**Address:** No. 2-1, Liuxian 1st Road, Xin' an Sub-District, Baoan District, Shenzhen,Guangdong Province, China 518101  
**European Representative :** Qarad EC-REP b.v.b.a., Pas 257, B-2440 Geel, Belgium

**Products Information:**

Item name	Reference number
BIOEASY™ 2019-Novel Coronavirus (2019-nCoV) Ag GICA Rapid Test	YRLG22201025,YRLG22201050,YRLG22201100
BIOEASY™ Diagnostic Kit for 2019-Novel Coronavirus(2019-nCoV) Ag (Time-resolved Fluorescence Immunochromatographic Assay)	YRLF04401025,YRLF04401050,YRLF04401100
BIOEASY™ 2019-Novel Coronavirus (2019-nCoV) IgG/IgM GICA Rapid Test	YRLG22301025,YRLG22301050,YRLG22301100
BIOEASY™ 2019-Novel Coronavirus (2019-nCoV) Ab GICA Rapid Test	YRLG22501025,YRLG22501050,YRLG22501100
BIOEASY Diagnostic Kit for Novel Coronavirus(2019-nCoV) Nucleic Acid (RT-PCR)	YRLP00101050
Bioeasy™ Immunofluorescence Analyzer (EASY-11)	YRLE01105

**Classification(IVDD):** Others

The manufacturer ,herewith ,declares that the product as specified above meets the applicable provisions of the following the European Directive 98/79/EC and Standards for in vitro Diagnostic Medical Devices.

**Applicable Standards:** EN ISO13485:2016 EN ISO13612:2002  
EN ISO14971:2012 EN ISO23640:2015  
EN ISO18113-1:2011 EN ISO18113-2:2011  
EN ISO15223-1:2016 EN ISO13641:2002

**Place,date of issue:** Shenzhen,P.R.China,Feb.01,2020

**Signature(Quality Director)**



