BIOEASY

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: 5.1.2e
European Representative : 5.1.2e

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(General Manager)

5.1.2e

CE