SJ-CE-271-007 V1

Declaration of Conformity

Manufacturer:
Zhuhai Encode Medical Engineering Co., Ltd
No.020, Honghui 2nd Rd., Hongqi Industrial Zone, Jinwan District, 519090 Zhuhai, P.R China
Tel:86-756-3981528 Fax86-756-3983908

European Representative:
Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf, Germany

Product Name:
Novel Coronavirus(COVID-19)IgG/IgM Rapid Test Device (Colloidal Gold)
EDMA-Code: 15 04 80 90

Classification:
Other device, not in annex II, not for self-testing, not for performance evaluation.

Conformity Assessment Route: Annex III (VIDD 98/79/EC)
We herewith declare under sole responsibility that the mentioned product meets the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical device. All supporting documentations are retained at the premises of the manufacturer.

General applicable directive:
Novel Coronavirus(COVID-19)IgG/IgM Rapid Test Device (Colloidal Gold)

Standards Applied:

EN 13612:2002	EN ISO 13485:2016	EN ISO 15223-1:2016
EN ISO 18113-1:2011	EN ISO 23640:2015	EN ISO 14971:2012
EN 13641:2002	EN ISO 18113-2:2011	EN ISO 17511:2003

First Start of CE-MARK: Feb. 19, 2020

Signature: Managing Director

Place, Date of Issue: Zhuhai,Feb.19,2020