

Declaration of Conformity

according to the In Vitro



Diagnostic Medical Devices Directive 98/79/EC



Manufacturer:	Zhuhai Encode Medical Engineering Co., Ltd
Address:	NO.020,Honghui 2nd Rd, Hongqi Industrial Zone,Jinwan District, Zhuhai, P.R China

We declare under our sole responsibility that

the IVD Medical Device	Product Name	:	SARS-CoV-2 IgG/IgM Rapid Test
	Type/model, batch/serial number, possibly sources and number of items <small>(Where applicable)</small>	:	1/5/10/20/25/40/50
of class	according to directive 98/79/EC	:	other

meets all the provisions of the directive 98/79/EC which apply to it.

Conformity assessment procedure	IVDD 98/79/EC, Annex III
EU Representative	Name: Prolinx GmbH Add: Brehmstr. 56, 40239, Duesseldorf Germany



Zhuhai, 2020-03-16
(place and date)

GM *SUN Yifeng*
(name and signature, function)