

DECLARATION OF CONFORMITY

Manufacturer Guangdong Longsee Biomedical Co.,Ltd.
Address 5/F Building A, No.83, Ruihe Road, Huangpu District, 510000, Guangzhou, China

European Representative MedPath GmbH
Address Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Product Information 2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)
Model code LS-C-T-008, LS-C-T-009
Classification Other IVD Device

Registration Number in German DIMDI Database DE/CA61/1M50/294
Conformity Assessment Route: Annex III

General

Applicable

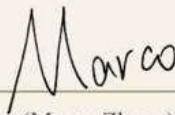
Directives: In vitro diagnostic medical devices Directive: 98/79/EC

Standards	EN13612:2002/AC: 2002	EN ISO13485:2016
Applied	EN ISO 23640:2015	EN ISO14971:2012
	EN 13641:2002	EN ISO18113-1:2011
	EN 15223-1:2016	EN ISO18113-2:2011

We, the manufacturer, hereby declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. The products meet prospective uses and all supporting documentations are retained under the premises of the manufacturer.

Place, date of issued: Guangzhou, P. R. China, May 10, 2021

Signature of Vice President:


(Marco Zhang)

