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

Standards Applied	EN13612:2002/AC: 2002	EN ISO13485:2016
	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

(Marco Zhang)

CE