

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/IM50/294
Conformity Assessment Route: Annex III

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 Zhang)

