

## 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

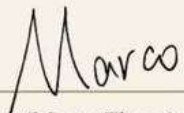
**Standards** EN13612:2002/AC: 2002 EN ISO13485:2016

**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)

