

DECLARATION OF CONFORMITY

Manufacturer: Zhuhai Lituo Biotechnology Co., Ltd.
Address: No.35, Yongan Three Road, Hongqi Town, Jinwan District,
Zhuhai, Guangdong, China.
European Representative: CMC Medical Devices & Drugs S.L
C/Horacio Lengo N° 18, CP 29006, Málaga-Spain
Product Name: COVID-19 Antigen Detection Kit(Colloidal Gold)
Model/Spec.: 25 Tests/ Kit;1 Test/Kit
Classification: (The way of conformity certification is applying for product CE
certification in accordance with 98/79/EC Annex I): Other IVD.

Conformity Assessment Procedures:

The products are a kind of in vitro diagnostic medical device, according to 98/79/EC Article 9
Conformity assessment procedures for Annexes III.

We here with declare that the above mentioned product meet the provisions of the following EC
Council Directives and Standards. All supporting documentations are retained under the premises
of the manufacturer and the EC Representative.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF
THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Standards:

98/79/EC; EN ISO13485:2016; EN ISO14971:2012; EN13612:2002/AC:2002;
EN13641:2002; EN ISO23640:2015; EN ISO17511-2003; EN ISO18113-1:2011;
EN ISO18113-3:2011; EN ISO15223-1:2012

All applicable harmonized Standards (published in the official Journal of the European
Communities).

Place/Date CE mark was affixed: Zhuhai Lituo Biotechnology Co., Ltd.



Signature: 

Xuean Yong

General Manager

Date:15 July,2020

