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, 5 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 COVID-19 Antigen Detection Kit (Colloidal Gold) is 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. The products comply with the essential requirements in accordance with Annex I of the In vitro Devices Directive 98/79/EEC.

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; EN13640:2002; EN ISO18113-1:2011;
EN ISO18113-3:2011; EN ISO15223-1:2016 MEDDEV 2.12 rev8: Dec. 2013.

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

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

CE

Signature: Yong Xuean

Xuean Yong

General Manager

22 August, 2021

Digitally signed by Moldoveanu Ruxanda
Date: 2021.10.06 17:14:09 EEST
Reason: MoldSign Signature
Location: Moldova