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: self-testing 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 p. 6. We here with declare that the above-mentioned product meets 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.

Conformity assessment was performed by POLISH CENTRE FOR TESTING AND CERTIFICATION Notified Body No. 1434, 469 Pulawska Street, 02-844 Warsaw, Company registered in the XIII Economic Division of the District Court of the Capital City of Warsaw under KRS No. 0000144813.

CE Certificate's details:

No.: 1434-IVDD-475/2021 Date of Issue: 26.10.2021

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 ISO 23640:2015; EN ISO18113-1:2011; EN ISO18113-4:2011; EN ISO15223-1:2012 ; EN13532 :2002.

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

CE 1434

Signature: Yongxuean

Xuean Yong

CEO

ZHUHAI LITUO BIOTECHNOLOGY CO., LTD. 珠海市丽拓生物科技股份有限公司

Place: Zhuhai, China

26th October. 2021