Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

Company Name: Shenzhen Lvshiyuan Biotechnology Co., Ltd.
Address: 101, 201, 301, D Building, No. 2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen 518120 China

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

List of Products:

1. SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- **ISO 9001: 2015**

Corporate Contact Information

COMPANY NAME: Shenzhen Lvshiyuan Biotechnology Co., Ltd.
COMPANY ADDRESS: 101, 201, 301, D Building, No. 2 Industrial Avenue, Buxin Village, Buxin Community Dapeng Subdistrict Office, Dapeng New District, Shenzhen 518120 China
COMPANY PHONE: +86 755 28438788
COMPANY FAX: +86 755 28938800
COMPANY EMAIL: s.gu@lsybt.com
RESPONSIBLE PERSON'S name: Jiang Yongqing
Position: Vice General Manager
SIGNATURE : Yongqing Jiang
Date : 2020/11/09
Stamp

European Authorized Representative:
Registered Address:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)