



## 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](mailto:s.gu@lsybt.com)

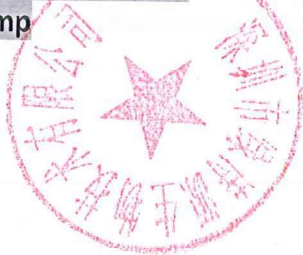
RESPONSIBLE PERSON'S name: Jiang Yongqing

Position: Vice General Manager

SIGNATURE :

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](mailto:mail@obelis.net)

Representative: Mr. Gideon ELKAYAM (CEO)