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

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Stamp

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Representative: Mr. Gideon ELKAYAM (CEO)

Datum: 17. Dezember 2021

Herstellererklärung

Wir, Shenzhen Lvshiyuan Biotechnology Co.,Ltd., als Hersteller erklären hiermit, dass Green Spring SARS-CoV-2-Antigen-Schnelltest-Set (kolloidales Gold) die folgenden von der WHO als besorgniserregend aufgeführten SARS-CoV-2-Virusvariante nachweisen kann.

WHO Bezeichnung	Pangolin Bezeichnung	Erstmaliger Nachweis
Variante Alpha	B.1.1.7	September 2020
Variante Beta	B.1.351	Mai 2020
Variante Gamma	P.1	November 2020
Variante Delta	B.1.617.2	Oktober 2020
Variante Omikron	B.1.1.529	November 2021

Da die Erkennungsstelle unseres SARS-CoV-2-Testkits das Nukleokapsid (N)-Protein-Antigen ist, befinden sich laut Forschung die Mutationsstellen der oben genannten Varianten, einschließlich anderer bekannter Virusvarianten, nicht auf der spezifischen Bindungsstelle unseres Testkits. Nach bekannten akademischen Meinungen haben diese Mutantenstellen keinen Einfluss auf die Nachweisfähigkeit des Green Spring SARS-CoV-2-Antigen-Schnelltest-Set (kolloidales Gold).

Wang Tangxin
CEO
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深圳市绿生物技术有限公司

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Comparative sensitivity evaluation for 122 CE-marked SARS-CoV-2 antigen rapid tests

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This study has been submitted as tandem manuscript together with the study of Puyskens A et al. “Establishment of an evaluation panel for the decentralized technical evaluation of the sensitivity of 31 rapid detection tests for SARS-CoV-2 diagnostics"

NOTE: This preprint reports new research that has not been certified by peer review and should not be used to guide clinical practice.