Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer:

Name: *HANGZHOU REALY TECH CO., LTD.*
Address:4th Floor, #12 Building, Eastern Medicine Town, Xiasha Economic & Technology Development,310018 Hangzhou, Zhejiang, P. R. China

Product/s	*Catalogue number*
Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (saliva)	*K590516D*

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III, except Point 6, of Directive

Applicable Standards: EN ISO 13485: 2016; EN ISO 15223-1:2016; EN ISO 14971: 2012; EN ISO 13612:2002; EN ISO 17511:2003; EN ISO 18113-1:2011; EN ISO 18113-2:2011, EN ISO 23640:2015.

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Luxus Lebenswelt GmbH, located at Kochstr.1,47877, Willich, Germany to act as our European Authorised Representative as defined in the aforementioned Directive.

Hangzhou 2020.12.15

(Place and date of issue)

Dean

(Signature and position)

Signed for and on behalf of the manufacturer

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Hangzhou Clongene Biotech Co., Ltd.
No. 1 Yichuang Road, Yuhang Sub-district
Yuhang District
311121 Hangzhou
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Design/development, Manufacture and Distribution of In-vitro Diagnostic Rapid Test of Fertility, Drug of Abuse, Infectious Diseases, Tumour Markers and Cardiac Markers

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-04-16
Certificate Registration No.:	SX 60137252 0001
An audit was performed. Report No.:	15073650 006
This Certificate is valid until:	2020-11-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-04-16

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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