

EU DECLARATION OF CONFORMITY

Manufacturer: Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
Area C, Building 2, No.365, Wuzhou Road,
Yuhang Economic Development Zone,
311100 Hangzhou,Zhejiang,China

European Authorized Representative: Shanghai International Holding Corp.GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: SARS-CoV-2 Antigen Rapid Test Cassette

Model: COVG-602ST

Classification: Self-testing device not listed under Annex II of Directive
98/79/EC

Notified Body: Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw

Notified Body No.: 1434

EC Certificate No.: 1434-IVDD-474/2021

Conformity assessment route: Annex III section 6 of Directive 98/79/EC
EN ISO 13485:2016, EN ISO 14971:2012,
EN 13532:2002, EN ISO 23640:2015, EN ISO 13612:2002,

Applicable Standards: EN ISO 17511:2003, EN 13975:2003,
EN ISO 18113-1:2011, EN ISO 18113-4:2011,
EN ISO 15223-1:2016, EN 13641:2002,EN 62366:2008

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.

Hangzhou, October 23, 2021

Place, date

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD.



General Manager

Legally binding signature, Position