

# 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

**Applicable Standards:** EN ISO 13485:2016, EN ISO 14971:2012,  
EN 13532:2002, EN ISO 23640:2015, EN ISO 13612:2002,  
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*