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.

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

Hangzhou, October 23, 2021
Place , date

General Manager
Legally binding signature, Position