EU DECLARATION OF CONFORMITY

Manufacturer:	Sejoy Biomedical Co., Ltd. Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,Hangzhou City 311100 Zhejiang China
European Authorized Representative:	Shanghai International Holding Corp.GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette
Specification:	COIF-522
Classification:	Other device not listed under Annex II and self-testing of Directive 98/79/EC
Conformity assessment route:	Annex III,except Point 6,of Directive 98/79/EC
Applicable Standards:	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 23640:2015, EN ISO 13612:2002, EN ISO 17511:2003, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2021, EN 13641:2002

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.

浙江世佳生物医疗有限公司
SEJOY BIOMEDICAL CO.,LTD.

Hangzhou, August 23, 2023
Place,date

General Manager
Legally binding signature, Position