

EU DECLARATION OF CONFORMITY

Manufacturer: Hangzhou Sejoy Electronics & Instruments 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 14971:2012,
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 15223-1:2016, 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.

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

Hangzhou, April 09, 2021

Place, date

 General Manager

Legally binding signature, Position