

EC DECLARATION OF CONFORMITY

Manufacturer: CORDX, INC.
9540 Waples St Unit C, San Diego, CA 92121, USA

European Representative: Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany

Manufacturing Site: Core Technology Co., Ltd.
Room 100 C Building No. 29 Life Park Rd, Changping District, Beijing
102206, P. R. China

Trade Name: Influenza A/B+COVID- 19/RSV Combo Ag Test

Product Model(s): See the Attachment I

Classification: **for self-testing of IVDD**

Conformity Assessment Route: **IVDD Annex III - Section 6**

We herewith declare that the above mentioned products meet the transposition into European regulations, the provisions of the following EC Council Directives and Standards. The declaration of conformity is exclusively under the sole responsibility of CorDx, Inc. (Manufacturer).

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Notified Body:

CeCert Sp. z o.o.(CE 2934)

EC Certificate No . CeCert/064/W/E.3

Validity date: 02.05.2022 – 26.05.2025

Edition issue date: 16.12.2022

Harmonized standards:

EN ISO 13485:2016, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002,
EN ISO 15223-1:2016, EN ISO 14971:2019, EN ISO 23640:2015,
EN 13641:2002, EN 13532:2002, EN 62366-1:2015.

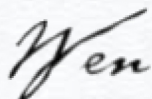
Date: Dec 16, 2022

Name: Amber Wen

Title: Regulatory Affairs Manager

Position: San Diego, USA

Signature:



YHX