

CERTIFICATE

DIRECTIVE 98/79/EC

EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

CorDx, Inc.

9540 Waples St Unit C, San Diego, CA 92121, USA

in vitro diagnostic medical device for self-testing

**Influenza A/B+COVID-19/RSV
Combo Ag Test**

catalogue numbers:

BP292-01, BP292-02, BP292-04, BP292-05, BP292-25

in term of the design conforms to the requirements of Annex III
section 6 to Directive 98/79/EC (as amended) implemented into Polish
Law, as evidenced by the assessment conducted
by CeCert Sp. z o.o.

CE

2934

Validity date: 02.05.2022 – 26.05.2025

Issue date: 02.05.2022

Check it



CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

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/RSVCombo Ag Test

Product
See the Attachment I
Model(s):

Classification: for self-testing of IVDD

Conformity Assessment Route:IVDD Annex III - Section 6

Basic UDI-DI: 0850042559BC2920FZ

We herewith declare that the above mentioned products meet the transposition into national law, 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.2

Validity date: 02.05.2022 – 26.05.2025

Edition issue date: 15.09.2022

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, EN62366-1:2015.

Date: Sep 16, 2022
Name: Amber Wen
Title: Regulatory Affairs Manager
Position: San Diego,USA
Signature:

