EC DECLARATION OF CONFORMITY

According to Directive 98/79/EC, on *in vitro* diagnostic medical devices

Manufacturer:	CorDx, Inc. 9540 Waples St Unit C, San Diego, CA 92121
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 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:

Medical Device Directive: Council Directive 98/79/EC concerning in vitro diagnostic medical devices (IVDD 98/79/EC).

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.

Notified Body: CeCert Sp. z o.o.
(CE 2934)
Certificate No.: CeCert/064/W/E.1
Issue date: 02.05.2022
Expiry date: 27.05.2025

Date:	2022-05-02	Version:	V1.1
Name:	Wen Mei	Title:	Regulatory Affairs Manager
Position:	Beijing	Signature:	

EC Declaration of Conformity

Attachment I: Product Name and Model(s)

No.	Product Name	Packaging Specification	Catalogue Number
1	Influenza A/B+COVID-19/RSV Combo Ag Test	1 test/soft pack	BP292-04
2		1 test/box	BP292-01
3		2 tests/box	BP292-02
4		5 tests/box	BP292-05
5		25 tests/box	BP292-25

-END-