

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**

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.1

Validity date: 02.05.2022 – 26.05.2025

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.

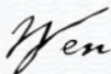
Date: Aug 8, 2024

Name: Amber Wen

Title: Regulatory Affairs Manager

Position: San Diego, USA

Signature:



Attachment I: Product Name and Model(s)

Product Name	Brand	Packaging Specification	Catalogue Number
Influenza A/B+COVID-19/RSV Combo Ag Test	Coretests	1 test/box	BP292-01
		2 test/box	BP292-02
		1 test/soft pack	BP292-04
		5 test/box	BP292-05
		25 test/box	BP292-25
	CorDx	1 test/box	BC292-01
		2 test/box	BC292-02
		5 test/box	BC292-05
		25 test/box	BC292-25
		1 test/box	BC292-03
		1 test/box	BC292-06
	HW	1 test/box	HWP292-01
		5 test/box	HWP292-05
		25 test/box	HWP292-25
	TGS Velox Ag	1 test/box	TGS-01
		5 test/box	TGS-05
		25 test/box	TGS-25
	Diather	1 test/box	DP292-01
	Milapharm	1 test/box	MP292-01
	MyBio	1 test/box	MY-01
		2 test/box	MY-02
		5 test/box	MY-05
		25 test/box	MY-25
	Accufast	1 test/box	AF-01
		2 test/box	AF-02
		5 test/box	AF-05
		25 test/box	AF-25
	RapiChek	1 test/box	RC292-01
		2 test/box	RC292-02
		5 test/box	RC292-05
	Testera	1 test/box	TT292-01

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