

# 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

# The list of devices covered by the scope of this Certificate is included in Annex 1

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.



Validity date: 02.05.2022 – 26.05.2025 Edition issue date: 16.12.2022

#### Check it



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

CeCert Sp. z o.o. ul. Warecka 11A 00-034 Warszawa

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Certificate no: CeCert/064/W/E.3



# ANNEX 1

### TO THE CERTIFICATE NO. CECERT/064/W/E.3

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/064/W/E.3:

Device Name	Brand	Catalogue Number
Influenza A/B+COVID-19/RSV Combo Ag Test	Coretests	BP292-01
		BP292-02
		BP292-04
		BP292-05
		BP292-25
	CorDx	BC292-01
		BC292-02
		BC292-05
		BC292-25
	нพ	HWP292-01
		HWP292-05
		HWP292-25
	TGS Velox Ag	TGS-01
		TGS-05
		TGS-25
	Diather	DP292-01
	Milapharm	MP292-01
	МуВіо	MY-01
		MY-02
		MY-05
		MY-25
	Accufast	AF-01
		AF-02
		AF-05
		AF-25
	RapiChek	RC292-01
		RC292-02
		RC292-05

#### Check it



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