Warsaw, 18.02.2025

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

CorDx, Inc.
9540 Waples St Unit C,
San Diego, CA 9212, USA

Ref: CeCert/701/2025

Approval of the Change

CeCert Sp. z o.o., Warecka 11A, 00-034 Warsaw, Poland, a notified body (ID number 2934) in the scope of Directive 98/79/EC of the European Parliament and of the Council concerning in vitro diagnostics medical devices, states as fallows.

On 02.05.2022, CeCert issued the EC certificate of conformity no. CeCert/064/W/E.1 stating 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 in term of the design conforms to the requirements of Annex III section 6 to Directive 98/79/EC. This letter is a supplement to the above-mentioned certificate of conformity and should be used together with it.

On 14.09.2022, CeCert, after assessment of the change (ref. no. 194A/2022) proposed by the manufacturer, approved this change and therefore additional labels and IFUs for new, additional brands under which the above-mentioned device was to be placed on the market. Therefore, it should be stated that the above-mentioned certificate of conformity after approval of this change covers the following brands and catalog numbers assigned to them:

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
	HW	HWP292-01
		HWP292-05
		HWP292-25
	TGS Velox Ag	TGS-01
		TGS-05
		TGS-25

On 16.12.2022, CeCert, after assessment of the change (ref. no. 194B/2022) proposed by the manufacturer, approved this change and therefore another additional labels and IFUs for new, additional brands under which the above-mentioned device was to be placed on the market. Therefore, it should be stated that the above-mentioned certificate of conformity after approval of this change covers the following brands and catalog numbers assigned to them:

Device Name	Brand	Catalogue Number
Influenza A/B+COVID-19/RSV Combo Ag Test	Diather	DP292-01
	Milapharm	MP292-01
	MyBio	MY-01
		MY-02
		MY-05
		MY-25
	Accufast	AF-01
		AF-02
		AF-05
		AF-25
	RapiChek	RC292-01
		RC292-02
		RC292-05

On 08.04.2024, CeCert, after assessment of the change (ref. no. 194C/2022) proposed by the manufacturer, approved this change and therefore another additional labels and IFUs (also

for new, additional brand) under which the above-mentioned device was to be placed on the market. Therefore, it should be stated that the above-mentioned certificate of conformity after approval of this change covers the following brands and catalog numbers assigned to them:

Device Name	Brand	Catalogue Number
Influenza A/B+COVID-19/RSV Combo Ag Test	CorDx	BC292-03
	Testera	TT292-01

On 09.08.2024, CeCert, after assessment of the change (ref. no. 194E/2022) proposed by the manufacturer, approved this change and therefore another additional labels and IFU with which the above-mentioned device was to be placed on the market. Therefore, it should be stated that the above-mentioned certificate of conformity after approval of this change covers the following brand and catalog number assigned to it:

Device Name	Brand	Catalogue Number
Influenza A/B+COVID-19/RSV Combo Ag Test	CorDx	BC292-06

On 18.02.2025, CeCert, after assessment of the change (ref. no. 194F/2022) proposed by the manufacturer, approved this change and therefore approved:

a) new multilingual IFUs for brand "RapiChek" (Catalogue Numbers: RC292-01, RC292-02, RC292-05),
b) new labels and IFU for brand "Diather" (Catalogue Number: DP292-01),
c) new labels and IFU for brand "Milapharm" (Catalogue Number: MP292-01),
d) and another additional labels and IFU with which the above-mentioned device was to be placed on the market and therefore, it should be stated that the above-mentioned certificate of conformity after approval of this change covers the following brand and catalog number assigned to it:

Device Name	Brand	Catalogue Number
Influenza A/B+COVID-19/RSV Combo Ag Test	CorDx	BC292-07

At the same time, CeCert states, after a thorough assessment, that in the light of the provisions of the document MDCG 2022-6 "*Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR*" implementation of above-mentioned changes do not represent a significant change in design or intended purpose of above-mentioned device under IVDR Article 110(3). The certificate of conformity no. CeCert/064/W/E.1 remains valid after the date of application of the IVDR, but no longer than its expiry date, i.e. until 26.05.2025, unless other provisions stipulate otherwise.

Sincerely,

Director of in Vitro Diagnostic Medical Devices Certification Department