

EC DECLARATION OF CONFORMITY

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

European Representative: Wellkang Ltd.
Enterprise Hub, NW Business Complex, 1 Beraghmore Rd.
Derry, BT48 8SE, N. Ireland, UK

Manufacturing Site: Core Technology Co., Ltd.
Room 100 C Building No.29 Life Park Rd, Changping District,
Beijing 102206, P.R.China

Trade Name: COVID-19 Ag Test

Brand REF Number

Accu News: COV-Ag01, COV-Ag02, COV-Ag03, COV-Ag04,
COV-Ag05, COV-Ag07, COV-Ag10, COV-Ag25.

Coretests: BP291-01, BP291-02, BP291-03, BP291-04,
BP291-05, BP291-07, BP291-10, BP291-25.

Accufast: AF-01, AF-02, AF-03, AF-05, AF-07, AF-10, AF-25.

Axnar: 1000, 1001.

BISAF: CTC19LP-1, CTC19LP-5.

Classification: **for self-testing of ANNEX II of IVDD**

Conformity Assessment Route: **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. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Notified Body: **POLISH CENTRE FOR TESTING AND CERTIFICATION**
(CE1434)

EC Certificate No. 1434-IVDD-522/2021

Harmonized standards:

EN ISO 13485:2016、 EN ISO 18113-1&4:2011、 EN 13612:2002、
EN ISO 15223-1:2016、 EN ISO 14971:2012、 EN ISO 23640:2015、
EN ISO 17511:2003、 EN 13641: 2002、 EN 13532:2002、 EN 62366:2015.

Date: Dec 23 , 2021

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Title: Regulatory Affairs Manager

Position: San Diego, USA

Signature: 