

EC DECLARATION OF CONFORMITY

Manufacturer: CORDX, INC.
9540 Waples Street Unit C, San Diego, CA 92121, USA

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

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-005/2022

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: Oct 03, 2022

Name: Amber Wen

Title: Regulatory Affairs Manager

Position: San Diego, USA

Signature: 

Attachment I: Product Model(s)

| No. | Brand | Packaging Specification | Catalogue Number |
|-----|--------------|-------------------------|------------------|
| 1 | Accu News | 1 test/soft pack | COV-Ag04 |
| | | 1 test/box | COV-Ag01 |
| | | 2 tests/box | COV-Ag02 |
| | | 3 tests/box | COV-Ag03 |
| | | 5 tests/box | COV-Ag05 |
| | | 7 tests/box | COV-Ag07 |
| | | 10 tests/box | COV-Ag10 |
| | | 25 tests/box | COV-Ag25 |
| 2 | Coretests | 1 test/soft pack | BP291-04 |
| | | 1 test/box | BP291-01 |
| | | 2 tests/box | BP291-02 |
| | | 3 tests/box | BP291-03 |
| | | 5 tests/box | BP291-05 |
| | | 7 tests/box | BP291-07 |
| | | 10 tests/box | BP291-10 |
| | | 25 tests/box | BP291-25 |
| 3 | Accufast | 1 test/box | AF-01 |
| | | 2 tests/box | AF-02 |
| | | 3 tests/box | AF-03 |
| | | 5 tests/box | AF-05 |
| | | 7 tests/box | AF-07 |
| | | 10 tests/box | AF-10 |
| | | 25 tests/box | AF-25 |
| 4 | Axnar | 1 test/box | 1000 |
| | | 5 tests/box | 1001 |
| 5 | BISAF | 1 test/box | CTC19LP-1 |
| | | 5 tests/box | CTC19LP-5 |
| 6 | TGS Velox Ag | 1 test/box | TG-01 |
| | | 5 tests/box | TG-05 |
| | | 25 tests/box | TG-25 |
| 7 | CorDx | 1 test/soft pack | BC291-04 |
| | | 1 test/box | BC291-01 |
| | | 2 tests/box | BC291-02 |
| | | 5 tests/box | BC291-05 |
| | | 25 tests/box | BC291-25 |

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