

Declaration of Conformity

Manufacturer: Beijing Hotgen Biotech Co.,Ltd.
 9th building, No.9 Tianfu Street, Biomedical Base,
 Daxing District, Beijing, 102600, P.R.China
European Representative: MedNet GmbH
 Borkstrasse 10, 48163 Muenster, Germany
Product Name: Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)
Analyte: Protein Antigen of 2019-nCoV
Brand name: Hotgen Biotech, CORA CHECK-19

Model	Trade name	Contains
Model A	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	1. Novel Coronavirus Antigen Test Cassette 2. Sample extraction buffer 3. Disposable virus sampling swab
Model B	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	1. Novel Coronavirus Antigen Test Cassette 2. Sample extraction buffer 3. Disposable virus sampling swab 4. Novel coronavirus 2019-nCoV Antigen Quality Control
Model C	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) - Saliva	1. Novel Coronavirus Antigen Test Cassette 2. Sample extraction buffer 3. Saliva collector 4. Biohazard specimen bag
Model D	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) - Saliva	1. Novel Coronavirus Antigen Test Cassette 2. Sample extraction buffer 3. Saliva collector 4. Biohazard specimen bag 5. Novel coronavirus 2019-nCoV Antigen Quality Control
Model E	SARS-CoV-2 Antigen Test (Colloidal Gold)	1. SARS-CoV-2 Antigen Test Cassette 2. Sample extraction buffer 3. Disposable virus sampling swab 4. Biohazard specimen bag



Classification: Others of ANNEX II of IVDD

Conformity Assessment Route: Annex III

We, Beijing Hotgen Biotech Co., Ltd., herewith declare on our solo responsibility 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

Harmonized standards:

EN ISO 13485:2016;

EN ISO 15223-1:2016;

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EN ISO 14971:2012;
EN ISO 18113-1:2011;
EN ISO 18113-2:2011;
EN 13612:2002;
EN ISO 17511:2003;
EN ISO 23640:2015;
EN 13641:2002;
EN 13975:2003;
EN 62366:2008.

Signature:

Name: Lin Changqing
Title: General manager





Place: Beijing, China.
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