

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: Coronavirus (2019-nCoV)-Antigentest -

Model Number: HGCG134S0101 (1T/Kit) HGCG134S0105 (5T/Kit)
HGCG134S0120 (20T/Kit) HGCG134S0140 (40T/Kit)

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany

Classification : Self-testing

Conformity Assessment Route: Annex III.6 of the directive 98/79/EC



We, 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 98/79/EC and Standards. All supporting documentations are retained under the premises of the manufacturer.

We, Beijing Hotgen Biotech Co., Ltd., is exclusively responsibility for the DOC.

Harmonized standards:

EN ISO 13485:2016; EN ISO 15223-1:2016; EN ISO 14971:2012; EN 13975:2003; EN ISO 18113-1:2011; EN ISO 18113-4:2011; EN 13612:2002; EN ISO 17511:2003; EN ISO 23640:2015; EN 13641:2002; EN 62366:2008; EN 13532:2002

(EC) Certificate(s) No. V9 089675 0006 Rev. 00

Start of CE-Marking 2021-08-05

Signature:

Name: Lin changqing

Title: General manager

Place: Beijing





EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
(Devices for self-testing)

No. V9 089675 0006 Rev. 00

Manufacturer:

Beijing Hotgen Biotech Co.,Ltd

9th Building, No. 9 Tianfu Street, Biomedical Base
Daxing District
102600 Beijing
PEOPLE'S REPUBLIC OF CHINA

Product:

In Vitro diagnostic devices for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex III (6). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V9 089675 0006 Rev. 00

Report No.:

BJ21071201

Valid from:

2021-08-04

Valid until:

2024-05-26

Date,

2021-08-04

Christoph Dicks
Head of Certification/Notified Body



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-245.10.07



Product Service

EC Certificate

EC Design-Examination Certificate
 Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
 (Devices for self-testing)

No. V9 089675 0006 Rev. 00

Model(s): **Coronavirus (2019-nCoV)-Antigentest-**

Facility(ies): Beijing Hotgen Biotech Co.,Ltd
 9th Building, No. 9 Tianfu Street, Biomedical Base, Daxing District,
 102600 Beijing, PEOPLE'S REPUBLIC OF CHINA

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