



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

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 II (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:

2021-03-04

Valid until:

2024-05-26

Date,

2021-03-04

Christoph Dicks
Head of Certification/Notified Body



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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

Model Name:

REF number:

Coronavirus (2019-nCoV)-Antigentest-

HGCG134S0101

Coronavirus (2019-nCoV)-Antigentest-

HGCG134S0105

Coronavirus (2019-nCoV)-Antigentest-

HGCG134S0120

Coronavirus (2019-nCoV)-Antigentest-

HGCG134S0140