Hotgen

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

CE 0123

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD 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

Model Name:	REF number:
Coronavirus (2019-nCoV)-Antigentest-	HGCG134S0101
Coronavirus (2019-nCoV)-Antigentest-	HGCG134S0105
Coronavirus (2019-nCoV)-Antigentest-	HGCG134S0120
Coronavirus (2019-nCoV)-Antigentest-	HGCG134S0140

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