

## 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

