

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

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
EN ISO 14971:2012
EN 13975:2003
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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