DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 089675 0005 Rev. 01

Holder of Certificate: **Beijing Hotgen Biotech Co.,Ltd**
9th Building, No. 9 Tianfu Street, Biomedical Base
Daxing District
102600 Beijing
PEOPLE'S REPUBLIC OF CHINA

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

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution and Service of Automated Immunoassay Analyzer, Up-converting Phosphor Immunoassay Analyzer, Up-converting Phosphor Technology Test Kits, Colloidal Gold Test Kits, Chemiluminescence Immunoassay Test Kits, Enzyme-Linked Immunoassay Test Kits.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 089675 0005 Rev. 01

Report No.: BJ20071201

Valid from: 2020-12-05
Valid until: 2023-12-04

Date, 2020-09-01

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

Declaration of Conformity

Manufacturer:

Name: Beijing Hotgen Biotech Co.,Ltd

Address: 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)

Novel Coronavirus 2019-nCoV Antigen Test (Up-converting Phosphor Immunochromatographic Technology)

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare 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

CE

Signature: Lin Changqing

Name: Lin Changqing

Title: General manager

Place: Beijing,China.

Date of Issue: Aug 27, 2020