DAkkS
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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 089675 0005 Rev. 02

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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.**

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. 02

Report No.: BJ21071202

Valid from: 2021-07-09
Valid until: 2023-12-04

Date, 2021-07-09

Christoph Dicks
Head of Certification/Notified Body

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

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 089675 0005 Rev. 02

Applied Standard(s):

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

Facility(ies):

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

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.

Beijing Hotgen Biotech Co.,Ltd
No.25, Heshun Street, Biomedical Base Daxing District, 102600 Beijing, PEOPLE'S REPUBLIC OF CHINA

Production of Up-converting Phosphor Technology Test Kits, Colloidal Gold Test Kits.

Beijing Hotgen Biotech Co.,Ltd
4th Floor, 10th Building, No.9 Tianfu Street, Biomedical Base Daxing District, 102600 Beijing, PEOPLE'S REPUBLIC OF CHINA

Production of Up-converting Phosphor Technology Test Kits, Colloidal Gold Test Kits.

Beijing Hotgen Biotech Co.,Ltd
2nd&3rd Building, No.21 Tianrong Street, Biomedical Base Daxing District, 102600 Beijing, PEOPLE'S REPUBLIC OF CHINA

Production of Up-converting Phosphor Technology Test Kits, Colloidal Gold Test Kits.

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

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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

Acknowledgment Letter

12/11/2020

Hongrui Zhang
Beijing Hotgen Biotech Co., Ltd.
9th Building, No. 9 Tianfu Street
Biomedical Base, Daxing District
Beijing 102600
CHINA

Dear Hongrui Zhang:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA203090
Received: 12/11/2020
Applicant: Beijing Hotgen Biotech Co., Ltd.
Device: Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health