



REGISTRATION NO. 04720Q10118R0

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Beijing Beier Bioengineering co., Ltd

Registered Address: No.99, Chuangxin Road, Lucheng Industry Zone, Huangcun Town, Daxing District, Beijing,

Manufacturing Address: No.99, Chuangxin Road, Lucheng Industry Zone, Huangcun Town, Daxing District, Beijing,

Has been assessed and conformed to the following standard(s)
GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

Design, Development, Production and Service of in vitro diagnostic
(within administrative licenses).

Date of issue: March 27, 2020

Date of expiry: March 26, 2023

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**



中国认可



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 108818 0001 Rev. 00

Holder of Certificate: **Beijing Beier Bioengineering Co., Ltd.**
No.99 Chuangxin Road
Lucheng Industrial Development Zone, Huangcun Town
Daxing District
102612 Beijing
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production, Distribution and Sales of Enzyme-linked Immunosorbent Assay Kit, Colloidal Gold Kit, Chemiluminescent immunoassay Kit, Fluorescence RT-PCR Kit, Nucleic Acid Purification Kit, Substrate Solution for Automatic Immunoassay System, Cleaning Solution and General Staining Reagent for Immunology and in Situ Hybridization.

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 108818 0001 Rev. 00

Report No.: BJ20046001

Valid from: 2021-02-22
Valid until: 2024-02-21

Date, 2021-02-22

C.D.M.
Christoph Dicks
Head of Certification/Notified Body

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cu originalul*
[Signature]



Certificate

No. Q5 108818 0001 Rev. 00

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 Beier Bioengineering Co., Ltd.
No.99 Chuangxin Road, Lucheng Industrial Development Zone,
Huangcun Town, Daxing District, 102612 Beijing, PEOPLE'S
REPUBLIC OF CHINA

See Scope of Certificate

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cu originalul*

[Signature]

REPUBLICA MOLDOVA
SOCIETATEA CU RASPUNDERE LIMITATA
PENTRU FACTURI
S.R.L.
IDNO 1016600004084
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