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

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

TÜV SÜD
Product Service

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

.

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

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

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

TÜV SÜD 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, Chemiluminescentimmunoassay 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

Christoph Dicks
Head of Certification/Notified Body

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CERTIFICATE

EC Certificate No. 1434-IVDD-472/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Beijing Beier Bioengineering Co., Ltd
No. 99 Chuangxin Road, LuCheng Industrial Development Zone, HuangCun Town, Daxing District, 102612 Beijing, Pekin

in vitro diagnostic medical devices
for self-testing

Covid-19 Antigen Rapid Test Kit (short Nose) Ref. No. 600485
Covid-19 Antigen Rapid Test Kit (Saliva) Ref. No. 600486

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 20.10.2021 to 27.05.2024

The date of issue of the Certificate: 20.10.2021

The date of the first issue of the Certificate: 20.10.2021

CE 1434

Issued under the Contract No. MD-63/2021
Application No: 126/2021, 127/2021
Certificate bears the qualified signature.
Warsaw, 20.10.2021
Module A1
FBM-30-E_10

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.10.20 12:43:36 +02'00'

Vice-President