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

TÜV SÜD
Product Service

Certificate

No. Q5 082508 0009 Rev. 00

Holder of Certificate: **Hangzhou Deangel Biological Engineering Co., Ltd.**
Jinxing Cun, Yuhang Community
Yuhang District(Future Sci-Tech City)
311121 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Hangzhou Deangel Biological Engineering Co., Ltd.
Jinxing Cun, Yuhang Community, Yuhang District(Future Sci-Tech City), 311121 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

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

Scope of Certificate: **Design and Development, Production and Distribution of In vitro diagnostic for the Detection of Fertility, Pregnancy, Infectious Diseases, Abused Drugs for monitoring of therapeutic measures, Cardiac Makers**

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). See also notes overleaf.

Report No.: SH1876608

Valid from: 2019-03-29
Valid until: 2022-01-27

Date, 2019-03-29

Stefan Preiß

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

TÜV®

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

Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Our Ref:IVD000713

Dr Edward Wang
Wellkang Ltd
16 Castle Street
Dover
Kent
CT16 1PW

18 March 2020

Dear Dr Wang

IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATIONS 2002: REGULATION 44
Registration of manufacturers of *In-Vitro Diagnostic* Medical Devices and devices for Performance Evaluation

Thank you for informing the Competent Authority of the change to the original notification dated (date the registration was registered); ***Manufacturers*** **Name:- Hangzhou Deangel Biological Engineering Co., Ltd.** located at **Manufacturers Address:- Jinxing Cun, Yuhang Community, Yuhang District (Future Sci-Tech City), Hangzhou, Zhejiang, China 311121** for whom you are acting as the authorised representative and for supplying the medical device information.

The change(s) to your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "in vitro diagnostic medical device", and that you have classified it/them correctly taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG3 form and means that you should now be operating under the In Vitro Diagnostic Medical Devices Directive and the 2002 Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us as required by the Regulations. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the Regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any changes to:

- the company information
- additional generic groups of devices or, for Annex II or Self-Test devices, additional devices
- discontinuation of a generic group of devices or, for Annex II or Self-Test devices, discontinuation of devices

Please use RG3, the Registration form, to tell us about any of these changes. A ee of £70 is payable for each change or set of changes notified.

Thank you for registering the following generic groups of devices

1. ***Part 5: IVDs which are not Annex II and not self-test devices***
2.
3. ***For reagnets, reagent products, calibration and control materials:***
4. ***group by common technological characteristics and/or analytes***
5.
6. ***New products:***
7. ***None***
8.
9. ***For performance evaluation:***
10. ***None***
11.
12. ***Neither:***
13. ***FSH - Rapid Test***
14. ***LH - Rapid Test***
15. ***Other Drugs of Abuse/Toxicology Rapid Tests***
16. ***Amphetamines - Rapid Test***
17. ***Cannabinoids - Rapid Test***
18. ***Multiple Drugs of Abuse/Toxicology Rapid Tests***
19. ***BNP / proBNP - Rapid Test (including other Natriuric Peptides)***
20. ***Troponin I/T - Rapid Test***
21. ***Myoglobin - Rapid Test***
22. ***CK - MB / Myoglobin - Rapid Test***
23. ***Multiple Cardiac Markers***
24. ***C-Reactive Protein - Rapid Test***
25. ***Faecal Occult Blood (CC) IC =>12.03.90.04***
26. ***Other Bacteriology Rapid Tests***
27. ***Syphilis - Rapid Test***
28. ***Other Faeces Test***
29. ***H. Pylori - Rapid Test***
30. ***Adenovirus***
31. ***Rotavirus***
32. ***Other Viral Antibody Detection***
33. ***Strep A - Rapid Test***
34. ***Other Specific Proteins Rapid Tests***
35. ***Other Tumour Marker Rapid Tests***
36. ***Dengue Virus***
37. ***Coronavirus***
38.
39.
40. ***For other IVDs, group by appropriate indications***
41.
42. ***New products:***
43. ***None***
44.
45. ***For performance evaluation:***
46. ***None***
47.
48. ***Neither:***
49. ***None***
50.
51.
52. ***Part 6: IVDs which are Annex II or self-test devices***

53.
54. ***For reagnets, reagent products, calibration and control materials:***
55. ***group by common technological characteristics and/or analytes***
56.
57. ***New products:***
58. ***None***
59.
60. ***For performance evaluation:***
61. ***None***
62.
63. ***Neither:***
64. ***Chlamydia Rapid Test Device***
65. ***hGC One Step Pregnancy Test Strip/Device***
66.
67.
68. ***For other IVDs, group by appropriate indications***
69.
70. ***New products:***
71. ***None***
72.
73. ***For performance evaluation:***
74. ***None***
75.
76. ***Neither:***
77. ***None***
78.

If you have any queries regarding your registration, please do not hesitate to contact us.

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer