Medicines & Healthcare products Regulatory Agency

MHRA

Our Ref: IVD001178

Dr Edward Wang
Wellkang Ltd
16 Castle Street
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United Kingdom

MHRA
10 South Colonnade
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18 May 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 details of ***Manufacturers* Name:- New Gene (Hangzhou) Bioengineering Co., Ltd.** located at **Manufacturers Address:- Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang, China 310000** for whom you are acting as the authorised representative and for supplying the medical device information.

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 considering 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.

Please note this letter does not represent any form of accreditation, certifcation or approval by the UK Competent Authority.

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 of the following changes;

- 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

You should submit your change of registration via DORS with the required statutory fee, which should be accompanied with the information when it is supplied, (the fee is payable for each record notified, and you may place multiple changes on one record).

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.

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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. ***Coronavirus***
14. ***Multiple Drugs of Abuse/Toxicology Rapid Tests***
15.
16.
17. ***For other IVDs, group by appropriate indications***
18.
19. ***New products:***
20. ***None***
21.
22. ***For performance evaluation:***
23. ***None***
24.
25. ***Neither:***
26. ***None***
27.
28.
29. ***Part 6: IVDs which are Annex II or self-test devices***
30.
31. ***For reagnets, reagent products, calibration and control materials:***
32. ***group by common technological characteristics and/or analytes***
33.
34. ***New products:***
35. ***None***
36.
37. ***For performance evaluation:***
38. ***None***
39.
40. ***Neither:***
41. ***None***
42.
43.
44. ***For other IVDs, group by appropriate indications***
45.
46. ***New products:***
47. ***None***
48.
49. ***For performance evaluation:***
50. ***None***
51.
52. ***Neither:***
53. ***None***
54.

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

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer