Medicines & Healthcare products Regulatory Agency

MHRA

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

Our Ref:IVD000456

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:- Core Technology Co Ltd** located at **Manufacturers Address:- Room 100, C Building, No.29 Life Park Road, Changping District, Beijing China 1022206** 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. ***Amphetamines Group - Rapid Test***
14. ***Cocaine + Cocaine Metabolites - Rapid Test***
15. ***Amphetamines - Rapid Test***
16. ***Other Drugs of Abuse/Toxicology Rapid Tests & POC***
17. ***Cannabinoids - Rapid Test***
18. ***Barbiturates - Rapid Test***
19. ***Benzodiazepines - Rapid Test***
20. ***Methadone - Rapid Test***
21. ***Phencyclidine - Rapid Test***
22. ***Tricyclic Antidepressants - Rapid Test***
23. ***Opiates - Rapid Test***
24. ***Multiple Cardiac Markers***
25. ***Dengue - Rapid Test***
26. ***H. Pylori Antibody Assays***
27. ***H. Pylori Antigen Detection***
28. ***Plasmodium (Malaria) - Rapid Test***
29. ***Albumin (IC) inclu. uAlbumin***
30. ***Syphilis - Rapid Test***
31. ***Troponin I/T - Rapid Test***
32. ***Other Bacteriology Rapid Tests***
33. ***Coronavirus***
34.
35.
36. ***For other IVDs, group by appropriate indications***
37.
38. ***New products:***
39. ***None***
40.
41. ***For performance evaluation:***
42. ***None***
43.
44. ***Neither:***
45. ***None***
46.
47.
48. ***Part 6: IVDs which are Annex II or self-test devices***
49.
50. ***For reagnets, reagent products, calibration and control materials:***
51. ***group by common technological characteristics and/or analytes***
52.

53. New products:
54. None
55.
56. For performance evaluation:
57. None
58.
59. Neither:
60. HCG Pregnancy Test
61. LH Ovulation Test
62. Fecal Occult Blood (FOB) Test
63. FSH Test
64. One Step HIV 1+2 Test
65. One Step HBsAg Test
66. One Step HCV Test
67.
68.
69. For other IVDs, group by appropriate indications
70.
71. New products:
72. None
73.
74. For performance evaluation:
75. None
76.
77. Neither:
78. None
79.

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

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer