Medicines & Healthcare products Regulatory Agency

MHRA

Our Ref: IVD001117

Dr Edward Wang
Wellkang Ltd
16 Castle Street
Dover
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MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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 details of ***Manufacturers*** **Name:- Safecare Biotech (Hangzhou) Co., Ltd.** located at **Manufacturers Address:- Building 2/203, No.18 Haishu Rd. Cangqian Sub-district, Yuhang District, Hangzhou, Zhejiang China 311121** 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. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon the declaration submitted on online via the Devices Online Registration System (DORS) 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 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).

Digitally signed by Rusu Ghenadie
Date: 2024.04.22 08:55:07 EEST
Reason: MoldSign Signature
Location: Moldova

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. ***Multiple Drugs of Abuse/Toxicology Rapid Tests***
14. ***Amphetamines Group - Rapid Test***
15. ***Amphetamines - Rapid Test***
16. ***Barbiturates - Rapid Test***
17. ***Benzodiazepines - Rapid Test***
18. ***Cannabinoids - Rapid Test***
19. ***Cocaine + Cocaine Metabolites - Rapid Test***
20. ***Methadone - Rapid Test***
21. ***Opiates - Rapid Test***
22. ***Phencyclidine - Rapid Test***
23. ***Tricyclic Antidepressants - Rapid Test***
24. ***Other Drugs of Abuse/Toxicology Rapid Tests & POC***
25. ***Other Specific Proteins Rapid Tests***
26. ***Dengue - Rapid Test***
27. ***Faecal Occult Blood (CC) IC =>12.03.90.04***
28. ***Other Bacteriology Rapid Tests***
29. ***H. Pylori - Rapid Test***
30. ***Influenza A and /or B***
31. ***Plasmodium (Malaria) - Rapid Test***
32. ***Other Other Virology Rapid Tests***
33. ***Strep A - Rapid Test***
34. ***Strep B - Rapid Test***
35. ***Syphilis - Rapid Test***
36. ***Other Clin. Chem. Rapid Tests***
37. ***HCG - Rapid Test***
38. ***LH - Rapid Test***
39. ***Urine Multi-constituent Test Strips (Manual)***
40. ***Other Urine Testing***
41. ***Albumin (IC) inclu. uAlbumin***
42. ***Mycoplasma Antibody Assays***
43. ***Coronavirus***
44.
45.
46. ***For other IVDs, group by appropriate indications***
47.
48. ***New products:***
49. ***None***
50.
51. ***For performance evaluation:***
52. ***None***
53.
54. ***Neither:***
55. ***None***
56.
57.
58. ***Part 6: IVDs which are Annex II or self-test devices***

59.
60. For reagnets, reagent products, calibration and control materials:
61. group by common technological characteristics and/or analytes
62.
63. New products:
64. None
65.
66. For performance evaluation:
67. None
68.
69. Neither:
70. HCG Pregnancy Test
71.
72.
73. For other IVDs, group by appropriate indications
74.
75. New products:
76. None
77.
78. For performance evaluation:
79. None
80.
81. Neither:
82. None
83.

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

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer