Safeguarding public health

MHRA

Our Ref:**IVD000562**

Dr Edward Wellkang
Wellkang Ltd
Suite B
29 Harley Street
London
W1G 9QR

13 September 2011

Dear Dr Edward Wellkang,

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 for ***Manufacturers* Name:- Taigen Bioscience Corporation located at Manufacturers Address:- 3F,No.150, Sec 4 ChengeDe Road Taipei Taiwan, 111, Province of China** 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 fee of £70 is payable for each change or set of changes notified.

Thank you for registering the following generic groups of devices

Part 5: IVDs which are not Annex II and not self-test devices

For reagnets, reagent products, calibration and control materials: group by common technological characteristics and/or analytes

New products:
None

For performance evaluation:
None

Neither:
Other Hardware + accessories + consumables + software
Infectious Immunology - Reagents for DNA and or RNA extraction and preparation

For other IVDs, group by appropriate indications

New products:
None

For performance evaluation:
None

Neither:
None

Part 6: IVDs which are Annex II or self-test devices

For reagnets, reagent products, calibration and control materials: group by common technological characteristics and/or analytes

New products:
None

For performance evaluation:
None

Neither:
None

For other IVDs, group by appropriate indications

New products:
None

For performance evaluation:
None

Medicines and Healthcare products Regulatory Agency (MHRA)
151 Buckingham Palace Road London SW1W 9SZ UK
T 020 3080 6000 www.mhra.gov.uk

Neither:
None

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

Yours sincerely

Sean Williams
Regulatory Affairs Administrator

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Email: sean.williams@mhra.gsi.gov.uk