Safeguarding public health

Our Ref: IVD000670

Mr Peter Wei
Lotus Global Co Ltd
15 Alexandra Road
London
NW8 0DP
United Kingdom

28 February 2013

Dear Mr Peter Wei,

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:- Shanghai Sinovae Tech Co Ltd** located at **Manufacturers Address:- 1207 No 99 Feng Pu Avenue Feng Xian District Shanghai 201400 China** 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 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 reagents, reagent products, calibration and control materials: group by common technological characteristics and/or analytes

New products:

- ***Urine Single Test Strips (incl. tablets)***
- ***Urine Multi-constituent Test Strips***
- ***Other Specific Proteins Rapid Tests***
- ***Other Tumour Marker Rapid Tests***
- ***FSH - Rapid Test***
- ***HCG - Rapid Test***
- ***CH Hardware + accessories + consumables + software***
- ***LH - Rapid Test***
- ***Amphetamines Group - Rapid Test***
- ***Amphetamines - Rapid Test***
- ***Barbiturates - Rapid Test***
- ***Benzodiazepines - Rapid Test***
- ***Cannabinoids - Rapid Test***
- ***Cocaine + Cocaine Metabolites - Rapid Test***
- ***Methadone - Rapid Test***
- ***Opiates - Rapid Test***
- ***Phencyclidine - Rapid Test***
- ***Tricyclic Antidepressants - Rapid Test***
- ***Multiple Drugs of Abuse/Toxicology Rapid Tests***
- ***Other Drugs of Abuse/Toxicology Rapid Tests***
- ***C-Reactive Protein - Rapid Test***
- ***CK - MB / Myoglobin - Rapid Test***
- ***Myoglobin - Rapid Test***
- ***Troponin I/T - Rapid Test***
- ***BNP / proBNP - Rapid Test (including other Natriuric Peptides)***
- ***Multiple Cardiac Markers***
- ***D-Dimer Rapid Test***
- ***H. Pylori - Rapid Test***
- ***Strep A - Rapid Test***
- ***Syphilis - Rapid Test***
- ***Other Bacteriology Rapid Tests***
- ***Other Hepatitis Viruses Rapid Tests***
- ***Plasmodium (Malaria) - Rapid Test***
- ***Mononucleosis - Rapid Test***
- ***Influenza A and /or B***
- ***Dengue - Rapid Test***
- ***Other Other Virology Rapid Tests***

For performance evaluation:

- ***None***

Neither:

- ***None***

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 reagents, 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

Neither:
None

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

Yours sincerely

Barbara Clarke

Regulatory Affairs Administrator
Email from barbara.clarke@mhra.gsi.gov.uk