Medicines & Healthcare products Regulatory Agency

MHRA

Our Ref: CA017533

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Mr Peter Wei
Lotus Global co Ltd
1 Fourseasons Terrace
West Drayton
Middlesex
UB7 9GG
United Kingdom

05 May 2020

Dear Mr Wei

MEDICAL DEVICES REGULATIONS 2002: REGULATION 19
Registration of Persons Placing General Medical Devices on the Market

Thank you for informing the Competent Authority of the details of ***Manufacturers*** **Name:- MULTIBRANDS TRADING (SUZHOU) CO., LTD** located at **Manufacturers Address:- Room 313, Ruiyuan Building No. 58, Dongda Street, Suzhou China 215002** 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 "medical device", and that you have classified it/them as falling within Regulation 19 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.

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

Your registration is based upon your declaration on the RG2 form and means that:

For Manufacturers of Class I medical devices, Assemblers, and Sterilisers

You should now be operating under the Medical Devices Directive and the above 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.

For Manufacturers of Custom-made devices and Custom Made Active Implantable

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. 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 the following chargable changes:

- the company information e.g. name and address
- additional generic groups of devices (not individual products within an existing generic group)
- Change of authorised representative

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device from your registration record, change of contact person, postcode, telephone number and/or email address, for which payment of our statutory fee does not apply. Though, you are required to provide these non-chargeable changes in writing we will not provide an updated letter of

registration. As the updated information does not affect your regulatory obligations or the information published on our Public Access Registration Database (PARD).

Thank you for registering the following generic groups of devices:

Class I Devices:
Cotton Wool/Gauze/Non Woven/PVA(Ribbons/Swab/Buds)
Eye Occlusion Plasters/Shields And Corneal Shields

Custom Made Devices:
None

Products Covered By Article 12:
None

Please note that the name and address of manufacturers and authorised representatives and their devices that have been registered will be published on our Public Access Registration Database (PARD).

Should you have any queries regarding your registration please do not hesitate in contacting us.

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer