Safeguarding public health

MHRA

Our Ref: CA 009438

Mr M Zarif
XPOSA RESTAURENT
41-43 Park Street
Luton
Bedfordshire
LU1 3JX
United Kingdom

22 December 2006

Dear Mr M Zarif,

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:- Beauty Teck International** located at **Manufacturers Address:- Air Port Road Gohad Pur Sialkot-Pakistan** 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. 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 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

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 any changes to:

- the company information
- additional generic groups of devices (not individual products within an existing generic group)
- discontinuation of a generic group of devices.

Please use RG2, the Registration form, to tell us about any of these changes.

Thank you for registering the following generic groups of devices:

Class I Devices:
Dental Instruments (Re-Usable & Non-Powered)
Surgical Instruments (Re-Usable And Non-Powered)
Surgical Instrument Accessories

Custom Made Devices:
None

Products Covered By Article 12:
None

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

Yours sincerely

Sean Williams
Regulatory Affairs Administrator

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