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Medicines and Healthcare products Regulatory Agency

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Our ref: CA 008161

23 March 2004

Dear Mr D Iqbal,

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:- Laftan Trading International) located at **Maufacturers Address:- Haji**Pura Fateh Gerh Road 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



Head Office

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An Executive Agency of the Department of Health