



Our Ref: CA 010477

Mr Alan Henry Heeley
Heeley Surgical Ltd
04 Park Square
Thorncliffe Park
Sheffield
S35 2PH
UK

22 July 2008

Dear Mr Alan Henry Heeley,

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 company's details 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 regulations.

The information you provided has been recorded against the reference number shown at the bottom 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 the RG2, the Registration form, to tell us about any of these changes