



**Our Ref: CA015106**

Mr Ian Bird  
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**MHRA**

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[www.gov.uk/mhra](http://www.gov.uk/mhra)

**19 October 2015**

Dear Mr Ian Bird,

**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 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, 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 chargeable changes:**

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

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 (PARAD).

Thank you for registering the following generic groups of devices:

*Class I Devices:*  
*Standalone Software*

*Custom Made Devices:*  
*None*

*Products Covered By Article 12:*  
*None*

### **Confidentiality**

Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential unless you have chosen to trade using personal details. This change only applies to medical devices and does not affect In Vitro Diagnostic devices registration, which remain confidential under Article 19 of the In Vitro Diagnostic Directive 98/79EC.

**If your company name or that of a manufacturer that you represent is based on an individual's personal name it will be published unless you inform the MHRA that you would like the company name to remain confidential.**

**Likewise, if your company address or that of a manufacturer that you represent is the personal home address of an individual it will be published unless you inform the MHRA that you would like the company address to remain confidential.**

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

Yours sincerely



***Ms Angela Bartley***  
**European Regulatory Affairs (ERA2) Office Manager**

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