

**COMPETENT AUTHORITY (UK)**

**8**

EC MEDICAL DEVICES DIRECTIVES

**GUIDANCE NOTES FOR THE  
REGISTRATION OF PERSONS  
RESPONSIBLE FOR PLACING  
DEVICES ON THE MARKET**

(MEDICAL DEVICES REGULATION 2002 REGULATION 19)

Updated December 2008

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## WHY INFORM?

The Medical Devices Directive 93/42/EEC requires manufacturers or, their authorised representatives or others placing medical device(s) on the Community market, to provide certain information to a Competent Authority in a Member State where they have a registered place of business.

These notes explain who should and how to provide the information to the Competent Authority (UK).

The Competent Authority (UK) has published additional guidance notes for manufacturers specifically for class I and custom made devices and also systems and procedure packs.

## Changes to the Medical Devices Regulations

**Directive 2007/47/EC amends the Active Implantable Medical Devices Directive 90/385/EC and comes into force on 21 December 2008.** One change to the Directive especially affects persons responsible for placing and putting into service custom made active implantable medical device(s) on the EU market.

Article 1. 11 of Directive 2007/47/EC amends Article 10 of Directive 90/385/EC to include a requirement for manufacturers of custom made active implantable medical devices to provide the competent authority of the Member State in which they have their registered place of business details of their address, a description of the device(s) concerned, the product labelling and the instructions for use.

The revisions to the Directives have been transposed into UK law, under the Medical Devices (Amendment) Regulations 2008 and came into force on 21 December 2008. However the regulations only become mandatory on 21 March 2010. During this transitional period manufacturers of custom made active implantable medical devices or their designated authorised representatives are not required to register their details with the UK Competent Authority; However they may wish to and can do so by completing the RG2 form. In addition to the completed form, manufacturers or their authorised representatives must also provide the Competent Authority with a copy of the device label and the instructions for use that will accompany the device.

## WHO SHOULD APPLY?

You must register with one Competent Authority in a Member State in which you have your registered place of business if you:

- *manufacture class I or custom made devices and place them on the market under your own name, or trading name(s);*
- *fully refurbish class I devices, or label one or more ready made devices, with a view to placing them on the market under your own name;*
- *place devices bearing the CE marking on the market, under your own name in a system or a procedure pack within their intended purposes and within the limits of uses specified by their original manufacturers;*
- *sterilise, for the purpose of placing on the market under your own name, systems or procedure packs or other CE marked medical devices designed by the manufacturer to be sterilised before use;*
- *are the authorised representative of a manufacturer who does not have a registered place of business in the Community, or if you import and place on the Community market for a manufacturer who has no authorised representative in the Community, devices within the above listed categories.*

If you do not have a registered place of business in a Member State you must designate a person established in the Community to act on your behalf.

## WHEN TO INFORM?

You must inform the competent authority when you first apply the CE marking to your class I device(s). If you have a number of models and the CE marking procedure is being introduced over a period, you may if you wish, inform the UK Competent Authority of all devices when informing of the first CE marking.

Manufacturers of custom-made devices, systems or procedure packs, and sterilisation companies, should register no later than the first time they claim compliance with the Directive.

## **WHOM TO INFORM?**

If you are a registered business in the UK you may inform the UK Competent Authority at the address given at the end of these guidance notes. If you also have businesses in other Member States you may choose to inform one of them and not the UK, but you must inform one competent authority in which you have a registered place of business.

If your business is registered in another Member State and not the UK you should seek information from the competent authority in that Member State.

If you register in the UK the Competent Authority will acknowledge your registration, allocate and inform you of your registration number, which you should quote in all subsequent correspondence. There will be a single registration number, allocated for reference purposes only, covering all devices registered by the person responsible.

## **HOW MUCH WILL IT COST?**

There is currently a registration fee of £70.00 per registration or change of registration.

## **HOW TO APPLY?**

The UK Competent Authority has a designated form (Form RG2); we request its use or please supply the same details in the same order in a format you prefer.

## **CHANGES TO REGISTERED DETAILS?**

After we register your notification, you must tell us about any changes or additions to the registered details. You can also use form RG2 to tell us about this. Additional to you notifying us, we will regularly review our records and request confirmation of the registered information.

## **IS IT A MEDICAL DEVICE?**

For a number of products it is not clear if they are medical devices or not. The Commission has offered some guidance and at appendix A (loose leaf) there are a

number of examples of products that may or may not be medical devices depending on the claim(s) being made by the manufacturer.

## **FORM RG2**

### *About the Application*

The form provides guidance opposite each question, the following is additional information for some of the questions.

## **PART 1**

### **QUESTION 2**

If the notification is for further information or change of information, please provide your name and address for cross reference to ensure we select the correct record. If the notification is for a change of name or address it would be very helpful if you could indicate this in the box at 5.

### **QUESTION 3**

The “Other” covers persons who are placing devices manufactured by companies having no registered offices in any Member State and who are not the authorised representative of that manufacturer, e.g. an importer.

### **QUESTION 4**

The statement must be signed in all cases by an authorised signatory.

**NOTE:** WITHIN PART 2 AND PART 3 THERE ARE ITEMS MARKED WITH A \* ; IN THE CASE OF SUCH ITEMS, THE PROVISION OF THE INFORMATION REFERRED TO IS NOT A REQUIREMENT UNDER THE DIRECTIVE. HOWEVER THE UK COMPETENT AUTHORITY WOULD APPRECIATE THE INFORMATION BEING SUPPLIED.

## **PART 2**

### *Manufacturer's Information*

### **QUESTION 5**

The requirement to register does not refer to a [natural or legal] person re-sterilising devices already on the market, but would cover activities such as procedure packs incorporating reusable instruments being packaged with other devices and placed on the market under that [natural or legal] person's own name.

System and procedure pack manufacturer's should provide their own details, not the name and address of the manufacturers whose devices are incorporated in the system packs.

### **PART 3**

#### *Device Information*

### **QUESTION 6**

Class I devices which have a measuring function or designed to be sterilised before being placed on the market must have those procedures assessed by a notified body. Manufacturers of custom made devices may manufacture similar devices that fall into class IIa, IIb or III and where a notified body is involved in conformity assessment. That involvement may be relevant to the custom-made devices.

Persons who carry out sterilisation procedures require the assessment of their procedures by a notified body.

It would be helpful if you could indicate any relevant notified body involvement by giving the notified body identification numbers and what the notified body's assessment covers.

### **QUESTION(S) 7, 8, 9**

The Competent Authority (UK) propose that this description should be in the form of broad family group rather than detailed descriptions and to this end have prepared a list of devices with code letters. Appendix B (loose leaf).

It would be helpful if you could indicate by use of code letters the range of devices the application covers. If no suitable code letter appears appropriate, please provide at (a) the generic name(s) used by the manufacturer.

The list will be updated regularly as devices are registered so you may wish to contact the Competent Authority (UK) before completion of the application to check that you have the latest issue number.

## DOCUMENTATION REQUIRED

### THE DIRECTIVE REQUIRES MANUFACTURERS TO PREPARE FOR:

- **CLASS I DEVICES.** *A declaration of conformity and technical documentation (article 11(5), annex VII section 3, Council Directive 93/42/EEC).*
- **CUSTOM MADE DEVICES.** *A statement and documentation allowing an understanding of the design (article 11(6), annex VIII Council Directive 93/42/EEC) (annex 6 Council Directive 90/385/EEC).*
- *devices covered by ARTICLE 12. A declaration (article 12 Council Directive 93/42/EEC).*

There is no requirement to supply any of these documents when registering, however these may be inspected at any time by the Competent Authority for a period ending at least five years after the last product has been manufactured.

**NOTE:** WHERE NEITHER THE MANUFACTURER NOR HIS AUTHORISED REPRESENTATIVE ARE ESTABLISHED IN THE COMMUNITY, THE OBLIGATION TO ENSURE THAT THE TECHNICAL DOCUMENTATION CAN BE MADE AVAILABLE FALLS TO THE PERSON PLACING THE DEVICES ON THE COMMUNITY MARKET E.G. AN IMPORTER.

If you have difficulty in answering any of the questions you should first check the Directive and guidance notes. If still unclear the Competent Authority (UK) will try to help.

For general enquiries on the Directive  
Please contact:

Medicines & Healthcare products Regulatory Agency,  
European and Regulatory Affairs,  
Market Towers,  
1 Nine Elms Lane,  
London



SW8 5NQ

Tel: (020) 7084 3300

Fax: (020) 7084 3112

Email: [mail to:ERA@mhra.gsi.gov.uk](mailto:ERA@mhra.gsi.gov.uk)

Internet: <http://www.mhra.gov.uk>

For technical enquiries

Please contact:

Ms D Smolenska

Address as above

Tel: (020) 7084 3363

Completed RG2 forms should be returned to the Registration Scheme Office at the same address:

For general enquiries on registrations please contact the general helpline on:

Tel: (020) 7084 3318