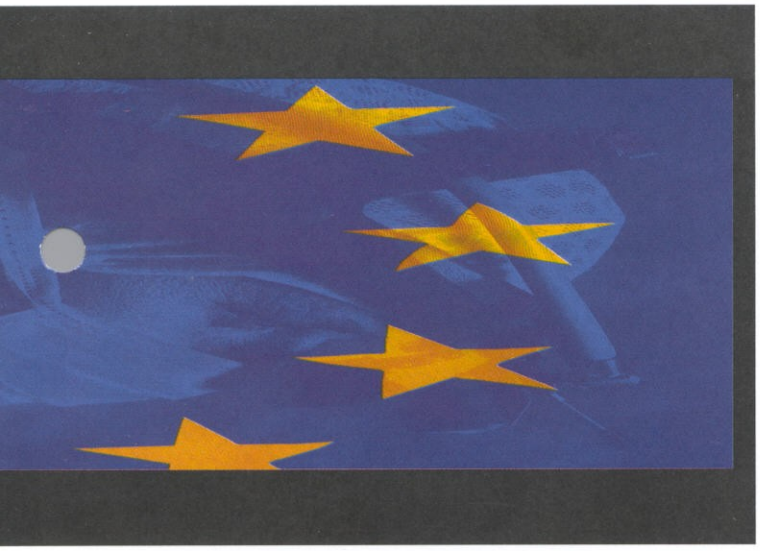
MEDICAL DEVICES AGENCY
COMPETENT AUTHORITY (UK)



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EC MEDICAL DEVICES DIRECTIVES

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

(MEDICAL DEVICES REGULATION 1994:REGULATION 14)

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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) is publishing additional guidance notes for manufacturers specifically for class I and custom-made devices and also systems and procedure packs.

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 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?

The Medical Devices Directive has a transitional period that commences 1 January 1995 and ends 13 June 1998. 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 have 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 chose 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 no registration fee at present.

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. In addition 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 addresses 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 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 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 enquires or forms
please contact:

Mrs Chris Bantock, 11/S/9
Medical Devices Agency, Hannibal House,
Elephant and Castle, London SE1 6TQ.

Tel 0171-972-8090 Fax 0171-972-8112

For technical enquires
please contact:

Mr R Higgins or Mr P Stonebrook
at the same address

Tel 0171-972-8185 or 0171-972-8386