MEDICAL DEVICES AGENCY
COMPETENT AUTHORITY (UK)

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EC MEDICAL DEVICES DIRECTIVES

GUIDANCE NOTES FOR MANUFACTURERS OF CLASS I MEDICAL DEVICES

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INTRODUCTION

The Medical Devices Regulations 1994 come into effect on 1 January 1995, with some transitional provisions until 14 June 1998. The Regulations implement the provisions of the Medical Devices Directive, 93/42/EEC, and require all medical devices to carry the CE marking unless they come within the definitions of custom-made devices or devices intended for clinical investigation.

Manufacturers, and others placing medical devices on the Community market should read The Medical Device Regulations 1994 to confirm that their products fall within the definition of a medical device, and also the device classification rules laid out in Annex IX of the Directive to confirm that they have correctly classified all of their products. Additional guidance on device classification is given in the Commission's document "Guidance to the Classification of Medical Devices" and by the Medical Device Agency's "Classify" software.

This brochure gives guidance on the requirements of the Medical Devices Regulations 1994 applicable to class I medical devices, including accessories but excluding devices intended for clinical investigation and custom-made devices.

This documentation must not be regarded as an authoritative statement of the law.

Further information and advice in individual cases may be sought from the Medical Devices Agency, the Competent Authority, whose address and telephone number are given in the Reference section at the end of this brochure.

The disadvantage of opting to comply with earlier United Kingdom practice during the transition period is that, if the manufacturer also exports the product to other member states, the manufacturer must additionally comply with other local requirements. Against this, products bearing the CE marking in conformity with the United Kingdom regulations should gain immediate access to the market in other member states.

COMPETENT AUTHORITY (U.K.)

A "competent authority" is the regulatory body within a member state that is charged with ensuring that the provisions of the Directive are correctly implemented. For medical devices in the United Kingdom, the Competent Authority is the Secretary of State for Health acting through the Medical Devices Agency.

It is the responsibility of the Competent Authority to ensure that all medical devices placed on the market or put into service in the United Kingdom meet the essential requirements laid down in the Directive. Within this responsibility the Competent Authority has a duty to maintain a register of:

- *UK manufacturers of class I devices, and of*
- *UK based representatives of non-EU manufacturers of class I devices.*

AUTHORISED REPRESENTATIVE

The Directive makes provision for manufacturers to appoint "authorised representatives" to act on their behalf in carrying out certain tasks.

All authorised representatives appointed by the manufacturer must be established (have a registered business) in the Community. The manufacturer may delegate tasks to the authorised representative, setting out the precise duties for which he is delegating his responsibility. The responsibility for actions by an authorised representative on behalf of the manufacturer, taken without exceeding their defined powers, then lies with the manufacturer and not with the representative.

SUMMARY OF THE REQUIREMENTS

Manufacturers of class I devices or their authorised representatives must:

- *review the classification rules to confirm that their products fall within class I (Annex IX of the Directive);*
- *check that their products meet the Essential Requirements (Annex I of the Directive);*

- *prepare relevant technical documentation (page 6);*
- *draw up the "EC Declaration of Conformity" (below) before applying the CE marking to their devices.*
- *implement and maintain corrective action and vigilance procedures (page 8).*
- *obtain notified body approval for sterility or metrology aspects of their devices, where applicable (page 8);*
- *make available relevant documentation on request for inspection by the Competent Authority (page 9);*
- *register with the Competent Authority (page 9);*
- *notify the Competent Authority, in advance, of any proposals to carry out a clinical investigation to demonstrate safety and performance of a device as required by the Regulations (page 7. Clinical Data). There is no transition period for this activity.*

CE MARKING

The Directive requires that, with the exception of custom-made devices and devices intended for clinical investigation, all medical devices must bear the CE marking of conformity (see Annex XII of the Directive) when they are placed on the market. The CE marking must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and where applicable on any instructions for use and sales packaging.

For "sterile" and "measuring" devices, the CE marking must be accompanied by the identification number of the notified body that has acted under the relevant conformity assessment procedure.

EC DECLARATION OF CONFORMITY

In order to affix the CE marking the manufacturer or his authorised representative must follow the EC declaration of conformity procedure referred to in Annex VII of the Directive. This procedure must be completed prior to placing the device on the market.
The "EC declaration of conformity" is the procedure whereby the manufacturer or his authorised representative prepares the required technical documentation, puts into place corrective action and vigilance procedures and declares that the products meet the essential requirements set out in Annex I of the Directive.

TECHNICAL DOCUMENTATION

The manufacturer must hold technical documentation that demonstrates the conformity of their products with the requirements of the Directive. This technical documentation must be prepared prior to drawing up the EC declaration of conformity and be kept available for review by the Competent Authority. The devices must meet the essential requirements set out in Annex I of the Directive which apply to them, taking account of the intended purpose of the devices concerned.

The technical documentation should be prepared following review of the essential requirements and must cover all of the following aspects.

- *DESCRIPTION. A general description of the product, including any variants (for example names, model numbers, sizes).*
- *RAW MATERIALS AND COMPONENT DOCUMENTATION. Specifications including, as applicable, details of raw materials, drawings of components and/or master patterns and any quality control procedures.*
- *INTERMEDIATE PRODUCT AND SUB-ASSEMBLY DOCUMENTATION. Specifications, including appropriate drawings and/or master patterns, circuits, and formulation specifications; relevant manufacturing methods; and any quality control procedures.*
- *FINAL PRODUCT DOCUMENTATION. Specifications, including appropriate drawings, and/or master patterns, circuits, and formulation specifications; relevant manufacturing methods; and any quality control procedures.*
- *PACKAGING AND LABELLING DOCUMENTATION. Packaging specifications and copies of all labels and any instructions for use.*
- *DESIGN VERIFICATION. The results of qualification tests and design calculations relevant to the intended use of the product, including connections to other devices in order for it to operate as intended.*

NOTE. IF THE MANUFACTURER CAN PROVIDE INFORMATION SHOWING THAT A SAFE DESIGN HAS BEEN ESTABLISHED FOR A NUMBER OF YEARS AND THAT THE PRODUCT HAS BEEN PERFORMING AS INTENDED DURING THAT TIME SUCH INFORMATION IS LIKELY TO BE SUFFICIENT TO COVER THIS REQUIREMENT.

- *RISK ANALYSIS. The results of risk analyses to review whether any risks associated with the use of the products are compatible with a high level of protection of health and safety and are acceptable when weighed against the benefits to the patient or user. If biocompatibility is relevant, for example for skin contact and invasive devices, a compilation and review of existing data or test reports based on the relevant standards is required.*

NOTE. IF THE MANUFACTURER CAN PROVIDE INFORMATION SHOWING THAT A SAFE DESIGN HAS BEEN ESTABLISHED FOR A NUMBER OF YEARS AND THAT THE PRODUCT HAS BEEN PERFORMING AS INTENDED DURING THAT TIME SUCH INFORMATION IS LIKELY TO BE SUFFICIENT TO COVER THIS REQUIREMENT.

- *COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS AND HARMONISED STANDARDS. A list of relevant harmonised standards (for example sterilization, labelling and information, biocompatibility, electrical safety, risk analysis, product group standards) which have been applied in full or in part to the products. If relevant harmonized standards have not been applied in full, then additional data will be required detailing the solutions adopted to meet the relevant essential requirements of the Directive.*

NOTE. HARMONISED STANDARDS ARE EUROPEAN STANDARDS PREPARED UNDER A MANDATE FROM THE EUROPEAN COMMISSION, REFERENCED IN THE OFFICIAL JOURNAL, AND DRAFTED SO THAT COMPLIANCE WITH THEIR REQUIREMENTS RELATE TO ONE OR MORE ESSENTIAL REQUIREMENTS OF THE DIRECTIVE. THESE STANDARDS HAVE SPECIAL STATUS IN THAT WHEN A MANUFACTURER CAN SHOW THAT HIS PRODUCTS MEET THE REQUIREMENTS OF THE STANDARD THERE IS A PRESUMPTION THAT THE PRODUCT CONFORMS TO THE ESSENTIAL REQUIREMENTS COVERED BY THE STANDARD. THE MANUFACTURER MAY CHOOSE TO PROVE CONFORMITY WITH THE ESSENTIAL REQUIREMENTS THROUGH USE OF THEIR OWN STANDARDS AND/OR OTHER RELEVANT PUBLISHED STANDARDS (ISO, EN, BS) BUT USE OF SUCH STANDARDS DOES NOT GIVE SIMILAR IMMEDIATE PRESUMPTION OF CONFORMITY TO THE ESSENTIAL REQUIREMENTS OF THE DIRECTIVE.

- *CLINICAL DATA. Many class I devices will not require a special clinical investigation to establish data on performance and safety or side effects. For products which have been established for a number of years and those which are modifications of such products, it is likely that a compilation and review of existing clinical experience would be sufficient to cover this requirement. However all manufacturers should review the intended use of the product and any medical claims that are being made to ensure that they have both adequate supporting test results and records of relevant experience.*

  Only in a minority of cases will a specifically designed clinical investigation be necessary in order to demonstrate device safety and performance as required by the Directive. Note that if a clinical investigation is required to justify use of a device, then the Competent Authority requires advance notification of the proposal. (Further information is available in Medical Devices Agency's brochure "Guidance Notes for Manufacturers on Clinical Investigation".)

- *RECORDS. Manufacturing and test records to show compliance with the defined procedures and specifications.*

SPECIAL PROVISIONS FOR STERILE CLASS 1 DEVICES

The manufacturer will need to approach a suitable notified body to obtain approval for the aspects of manufacturing concerned with securing and maintaining sterile conditions (such as environmental conditions for manufacturing, sterilization aspects, and packaging). Only one notified body can be approached at any one time for approval of particular product ranges and they will charge a fee for their services. Names and addresses of designated notified bodies can be obtained from the Medical Devices Agency (see Reference section).

SPECIAL PROVISIONS FOR CLASS 1 DEVICES WITH A MEASURING FUNCTION

Devices incorporating indicators which merely show a change in level or state without indicating a specific value, or indicate a specific value of no direct relevance to patient safety, do not exhibit a measuring function in terms of this Directive.

Class I devices are considered to have a measuring function if they either are syringes with volume indicators or measure a physiological parameter and display or indicate its value in a unit of measurement appropriate to the intended purpose. (Examples include thermometers, eye tonometers, lung function monitors including vital capacity meters).

NOTE. THE ABOVE IS AN MDA OPINION GIVEN IN THE ABSENCE OF OTHER GUIDANCE FROM THE COMMISSION.

The manufacturer will need to approach a suitable notified body to obtain approval to cover the aspects of manufacturing concerned with the conformity of the products with the metrological requirements (for example calibration and inspection). Names and addresses of designated notified bodies can be obtained from the Medical Devices Agency (see Reference section).

POST MARKET SURVEILLANCE, CORRECTIVE ACTION AND VIGILANCE PROCEDURE

The Directive seeks to improve the protection of health and safety of patients, users and others by reducing the likelihood of similar adverse incidents being repeated. Consequently, the Regulations require the manufacturer or his authorised representative to immediately notify the Competent Authority if they learn that a product has been involved in an incident:

- *that led to a death;*
- *that led to a serious injury or serious deterioration in the state of health of a patient, user or other person;*

- *that might have led to death, serious injury or serious deterioration in health;*

Additionally, the Competent Authority must be notified of

- *Any technical or medical reason leading to the systematic recall of a device.*

(Further information is given in the Medical Devices Agency's brochure "Guidelines on a Medical Devices Vigilance System").

Manufacturers must put in place, and keep updated, a documented procedure to review experience gained from devices on the market and to implement any necessary corrective action, commensurate with the nature and risks involved with the product. This is referred to as "post-market surveillance".

ADMINISTRATIVE PROVISIONS

A manufacturer or his authorised representative, (see Registration below) established in the United Kingdom must make the declaration of conformity and the technical documentation available for a period extending to at least five years after manufacture of the product. This is intended to enable any problems identified with a product to be fully investigated even though the product may no longer be available. It also allows for access by the Competent Authority, if it requires, to confirm that the declaration of conformity is valid.

In addition manufacturers of sterile or measuring devices must make available the information required for the particular conformity assessment procedure, such as notified body approvals and quality system documentation.

Manufacturers may also wish to note that under the Consumer Protection Act their liability for unsafe products lasts for 13 years and they may wish to preserve some of their technical documentation against this liability.

REGISTRATION

United Kingdom manufacturers of class I devices must inform the Competent Authority of the address of their registered place of business and provide a description of the devices concerned, such as the categories of devices and not the description of each model.

Manufacturers of class I devices outside of the Community must designate a representative within the Community. If this representative is established within the United Kingdom, they must inform the Competent Authority of the address of their registered place of business,

along with the description of the devices concerned.

Note that the name and address of such a representative must appear on either the label, outer packaging, or the instructions for use (Annex 1 clause 13.3(a) of the Directive).

The registration details should be submitted on the registration form RG2 (a copy is supplied with this brochure) once compliance with the requirements is claimed and the CE marking is first applied. Please read the accompanying "Guidance Notes for Registration" before completing the form.

The Competent Authority must subsequently be informed of new product categories when they are placed on the market.

REFERENCES

The Medical Devices Regulations 1994 †

Council Directive 93/42/EEC concerning medical devices. (OJ No L169, published 12 July 1993) †

Guidelines on the Classification of Medical Devices, med dev 10/93 ‡

Classify ‡ (requires Microsoft Windows® 3.1)

Guidance Notes for Manufacturers on Clinical Investigations to be carried out in the UK ‡

The Medical Devices Vigilance System: European Commission Guidelines ‡

† Available from HMSO (Tel: 0171 873 9090)

‡ Available from:
Medical Devices Agency, European and Regulatory Affairs
11th Floor, Hannibal House, Elephant & Castle
London SE1 6TQ.
Tel: 0171 972 8300 Fax: 0171 972 8112

MEDICAL DEVICES DIRECTIVE

The main purpose of the Directive is to harmonise national controls, so allowing free movement of medical devices throughout the European Union and EFTA whilst at the same time ensuring that all devices within the Union are reasonably safe in use.

The Directive covers most medical devices other than active implantable medical devices and in vitro diagnostics. As an illustration, devices covered range from first-aid bandages and tongue depressors through to hip joints and X-ray equipment.

The Directive takes effect in the United Kingdom on 1 January 1995, but there are special transitional provisions applying until 14 June 1998 (see next section).

The Directive:

- *specifies "essential requirements" which must be met before any device can be placed on the market;*
- *introduces controls covering the safety, performance, specification, design, manufacture and packaging of devices;*
- *specifies requirements for assessment of clinical investigation protocols, and the evaluation of any adverse incidents that occur;*
- *introduces a system of classifying devices, and applies a level of control which is matched to the degree of risk inherent in the device;*
- *empowers a Competent Authority to identify and designate "notified bodies" who check and verify that devices meet the relevant essential requirements.*

NOTE. NOTIFIED BODY INTERVENTION WILL NOT BE REQUIRED BY MANUFACTURERS OF CLASS I DEVICES UNLESS THE DEVICES ARE PLACED ON THE MARKET IN A STERILE CONDITION OR HAVE A MEASURING FUNCTION.

TRANSITION PERIOD

Although the provisions of the Directive take effect from 1 January 1995, manufacturers are allowed until 14 June 1998 to comply with most of the requirements.

During the period from 1 January 1995 to 13 June 1998 inclusive, manufacturers may choose to comply with the provisions of the regulations and ensure their products comply with the essential requirements. Alternatively they may choose to comply with existing United Kingdom requirements (for example, voluntary registration of the manufacturer under the Department of Health's Scheme or licenses under the Medicines Act).