THE SCOTTISH OFFICE

Department of Health



NHS Management Executive
St. Andrew's House
Edinburgh EH1 3DG
12th June 1998
Telephone 0131-244
Fax 0131-244 2683

Dear Colleague

**NATIONAL HEALTH SERVICES IN SCOTLAND**
**MANAGEMENT EXECUTIVE**

**MEDICAL DEVICES DIRECTIVE - CE-MARKING**

**Summary**

1. This letter reminds recipients of the effective date that the Medical Devices Directive comes fully into force. It draws attention to the main features of the legislation which safeguards patients and reassures the user regarding safety and product performance, as well as advising NHS Trusts and Health Boards of the action they need to take to ensure their organisation is prepared for compliance with this legislation.

**Action**

2. The contents of this letter should be brought to the attention of all managers concerned with the procurement of supplies, the manufacture of medical devices and the Senior Manager with responsibility for health and safety.

3. Purchasers of devices should ensure that their staff are aware of the requirements of this legislation and the significance of CE-marking and, that they are aware of the date the transitional period ends, 13 June 1998. NHS Trusts, Health Boards or NHS Agencies who manufacture medical devices should ensure that after 13 June 1998 they only place on the market devices which meet the relevant requirements of the Regulations.

4. Chief Executives should also ensure that their staff are aware of the requirements for reporting serious incidents to the manufacturers concerned, alongside their existing system for reporting to MDA Incident Reporting and Investigation Centre, as per MEL (1995)74, all adverse incidents involving medical devices.

**Addressees**

For action:
General Managers Health Boards
NHS Trust Chief Executives
General Manager, Common Services Agency

For information:
NHS ME Directors
Directors of Social Services
Director Scottish Healthcare Supplies

**Enquiries on Medical Devices Directive to:**

European and Regulatory Affairs
Hannibal House
Elephant and Castle
London SE1 6TQ
Tel: 0171-972-8300
24 hour information pack
Hotline 0171-972 -8203
Fax: 0171-972-8112
Technical Sterilisation enquiries to:
Steve Ellis
Tel: 0171-972-8235

**General Enquiries to:**

Mr Andrew Wong
Scottish Healthcare Supplies
Trinity Park House
South Trinity Road
EDINBURGH EH5 3SH
Tel: 0131-551-8402 (direct)
Fax: 0131-559-3922 (direct)

or

Mr Andy Nichol
Health Care Policy Division
Room 277
St Andrew's House
EDINBURGH EH1 3DG
Tel: 0131 244-2428
Fax: 0131 244-3487

Further copies of this MEL may be obtained from Andy Nichol

**The Medical Devices Directive**

5. From 14 June 1998 all medical devices marketed in Europe must comply with a European law - the Medical Devices Directive (93/42/EEC). The CE mark on a medical device shows that the product is declared to comply with this legislation which specifies requirements for safety and product performance.

6. The Directive was implemented into UK law by the Medical Devices Regulations (SI 1994 No 3017). Manufacturers of devices have had a three and a half year transition period to enable them to make any necessary changes to ensure compliance with the Regulations.

7. The Medical Devices Agency (MDA) is responsible for enforcing the UK Regulations and for investigating all reports of alleged breaches.

8. It is a requirement that manufacturers must have a system for reporting serious incidents involving their devices, to the Competent Authority under the Vigilance System. Manufacturers can obtain details from the MDA.

**The CE Mark**

9. The CE mark may only be affixed to a medical device when it complies with the Essential Requirements of the Regulations. To apply the mark, manufacturers are obliged by law to demonstrate that their products meet the Regulations and for certain classes of devices, have had their assessment conforming procedures checked by a Notified Body.

**Procurement of Medical Devices**

10. Medical devices placed on the market before 14 June 1998 and which have not been CE-marked may still be used as long as they are put into service prior to 30 June 2001 and thereafter continue to be used according to the manufacturer's intended purpose.

11. All medical devices, excluding in vitro diagnostics, placed on the market on or after 14 June 1998 must be CE-marked unless they are specific products manufactured to meet the needs of a named recipient (custom-made devices) or intended for clinical investigation only and are labelled to that effect. Products which are custom-made or intended for clinical investigation, and labelled to that effect, do not need the CE Mark. Purchasers of medical devices should continue to use MDA's evaluation service for up-to-date technical and user information on the safety, quality and performance of particular products.

**Manufacture or Placing on the Market of Medical Devices by the NHS**

12. Medical devices manufactured by an NHS Trust, Health Board or NHS Agency, e.g. prosthetics, laundered reusable theatre gowns and drapes, or Sterile Service Department (SSD) products, must comply with the Regulations if they are supplied to another separate legal entity (e.g. NHS Trust, NHS organisation, independent or voluntary health care provider or to anyone in the private sector). Further information is given in MDA Directives Bulletin

18A The Medical Devices Regulations: Implications on Healthcare and other Related Establishments, which can be obtained from the MDA.

13. European standards (EN 50103, EN 724, BS EN9000: Quality management and quality assurance and BS EN 46000: Specification for the application of the above to the manufacture of medical devices) support the Directive and lay down standards of manufacturing that represent good practice. To comply with health and safety and consumer protection legislation it is recommended that NHS in-house manufacturing operates to these standards even if products are not supplied to a separate legal entity. This is consistent with previous advice that in-house manufacture should operate to the same standards as industry and may provide a due diligence defence in the event of claims or litigation related to product liability.

Yours sincerely

**KEVIN J WOODS**
Director of Strategy and Performance Management

**ANNEX**

## 1. DEFINITIONS

1.1 **Medical Device** means "an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which -

a) is intended by the manufacturer to be used for human beings for the purpose of -

   i. diagnosis, prevention, monitoring, treatment or alleviation of disease

   ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap

   iii. investigation, replacement or modification of anatomy or of a physiological process, or

   iv. control of conception; and

b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means.

1.2 **Manufacturer** means "the person who is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless or whether these operations are carried out by that person himself or on his behalf by a third party".

1.3 **Placing on the market** means in relation to a device "the first making available in return for payment or free of charge of a new or fully refurbished device other than a device intended for clinical investigation, with a view to distribution, use, or both, on the Community market".

## 2. CLASSIFICATION OF PRODUCTS

2.1 The Directive covers a vast range of products from first-aid bandages and walking frames to CT scanner and non-active implants. While the use of many of these presents no danger, others may carry significant risks to patients or users. However, to apply the strictest controls to all products would require some manufacturers to set up additional, costly, and unnecessary procedures. It is important, therefore, that the level of control is matched, as far as possible, to the degree of risk inherent in the device. Attempts were therefore made to set the controls relative to the perceived risk in an effort to make them as relaxed as possible (thus easing the bureaucratic and financial burdens on business) and as strict as necessary (thus ensuring that the health of the patient and user is adequately protected).

2.2 Additional information - Medical Devices Agency; Directives Bulletin No 10; February 1995, *The classification rules*

## 3. VIGILANCE SYSTEM FOR REPORTING DEFECTS AND INCIDENTS INVOLVING DEVICES

3.1 The Aim of the vigilance system is to minimise risks to the health and safety of patients, users and others by reducing the likelihood of the same type of serious incident involving medical devices being repeated in different places at different times in the European Community.

3.2 This aim will be achieved through the evaluation of reported incidents by Member States, where appropriate, through the dissemination of information which could be used to prevent a re-occurrence of the incident, or to alleviate the consequences of such incidents, where appropriate, by the device being modified or taken off the market.

3.3 Manufacturers are required by the regulations to report all serious incidents to the Medical Devices Agency's Adverse Incident Centre (AIC).

3.4 Additional information -

a) Medical Devices Agency; Directives Bulletin No 3; February 1995 - *The Vigilance system*

b) MDA Safety Notice; SN 9801 *Reporting adverse incidents relating to Medical devices*.

## 4. CUSTOM-MADE DEVICES

4.1 If manufacturing is carried out in accordance with a duly qualified medical practitioner's written prescription for the sole use of a particular patient, then the product is considered to be a 'custom-made device'. The requirements of the Directive are not intended to interfere in any way with the clinical and professional responsibilities of the prescribed (eg Dentists, Optician etc). The activities carried out by the healthcare professional in supplying or fitting a custom-made device (eg preparation, impression taking, prescribing, final fitting and any adaption), are not considered to fall within the scope of the Medical Devices Regulations.

4.2 Some mass produced devices need to be adapted to meet the specific needs of a patient. These devices are not considered to be custom-made devices (eg contact lenses and stock footwear).

4.3 Additional information -

a) Medical Devices Agency; Directives Guidance No 8; *Guidance notes for the registration of persons responsible for placing devices on the market*

b) Medical Devices Agency; Directives Guidance No 9; *Guidance notes for manufacturers of custom-made devices*

c) Medical Devices Agency, Directives Guidance No 10; *Guidance notes for manufacturers of dental applicants (custom-made devices).*