THE SCOTTISH OFFICE

Department of Health

NHS
MEL(1996)43

NHS Management Executive
St. Andrew's House
Edinburgh EH1 3DG

9 May 1996

Dear Colleague

MEDICAL DEVICES AGENCY - DIRECTIVES BULLETINS

Summary

1. From 1 January 1993 a series of 3 Directives regulating the safety and marketing of medical devices throughout the European Community started to come into effect in the UK. These are

- The Active Implantable Medical Devices Directive
- The Medical Devices Directive
- The In Vitro Diagnostic Medical Devices Directive

2. The Medical Devices Agency is the Competent Authority (UK) and is authorised to act on behalf of the Secretary of State for Health to ensure that the requirements of the Medical Devices Directives are carried out.

Action

3. Chief Executives NHS Trusts, General Managers, Health Boards and other addressees are asked to draw the attention of all appropriate hospital and clinical staff to a series of Information Bulletins issued by the Medical Devices Agency which relate to the 3 Directives. A list of the Information Bulletins issued to date is given at Annex A.

4. We are aware that some but not all of the Bulletins have been distributed in Scotland. Further information and copies of the Bulletins can be obtained from Mr R M Gutowski, Department of Health, 14 Russell Square, London WC1B 5EP - Tel: 0171 6366811 (ext 3199)
Fax: 0171 436 2128.

Yours sincerely

Paul Wilson

PAUL WILSON

LTS09604

Addressees

For action:
Chief Executive
NHS Trusts

General Managers
Health Boards

General Manager
Common Services Agency

General Manager
State Hospitals Board
for Scotland

General Manager
Health Education Board
for Scotland

Executive Director
SCPMDE

Enquiries to:

Mr G Wildridge
NHS Management Executive
Room 277
St Andrew's House
EDINBURGH EH1 3DG

Tel: 0131-244 2433
Fax: 0131-244 3487

ANNEX A

MEDICAL DEVICES DIRECTIVES: MDA GUIDANCE DOCUMENTS

Information Bulletins

1. Information for manufacturers	March 1992
2. The CE Marking	July 1992
3. The Vigilance System	August 1992
4. Conformity Assessment Procedures	December 1992
5. Pre-Clinical Assessment Procedures	January 1993
6. The Notified Body	March 1993
7. The Competent Authority	April 1993
8. Information about the EC Medical Devices Directives	April 1993
9. The Citizen's Charter and a Code for Enforcement	August 1993
10. The Classification Rules	September 1993
11. EC and EFTA Member States (EEA Agreement)	June 1994
12. Sale and Supply of In Vitro Diagnostic Medical Devices	November 1994
13. Standards	November 1994
14. Compliance Cost Assessments	December 1994
15. The Medical Devices, Electromagnetic Compatibility and Low Voltage Directives	May 1995
16. Information about the Packaging and Packaging Waste Directive	May 1995
17. Medical Devices and Medicinal Products	May 1995
18. Activities of Healthcare Establishments (In-house Manufacture)	June 1995