EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations ("the Regulations") implement Council Directive 93/42/EEC ("the Directive") concerning medical devices.

The Directive is based on the Council resolution of 7 May 1985 on a new approach to technical harmonisation and standards. It lays down essential safety requirements which medical devices ("devices") must satisfy.

Regulation 3 specifies those products and substances which are not devices for the purposes of the Regulations.

Regulation 4 provides for the classification of devices into Classes I, IIa, IIb and III for the purposes of the Regulations.

Regulation 5 provides that devices placed on the market or put into service must comply with the relevant essential requirements as defined by reference to the essential requirements specified in Annex I of the Directive. Regulation 5 also sets out the factors to be taken into consideration in deciding whether a device meets the essential requirements.

Regulation 6 requires devices other than custom-made devices or devices intended for clinical investigation to bear the CE marking. Regulation 6 also prohibits the use of a mark which is likely to be confused with the CE marking.

Regulations 7, 8, 9 and 10 specify the procedures which manufacturers must follow for affixing the CE marking to devices.

Regulation 11 sets out the requirements to be satisfied for placing devices on the market as a system or procedure pack and for CE marked devices designed by manufacturers to be sterilised before use.

Regulation 12 contains general provisions relating to the procedures for affixing the CE marking to a device.

Regulation 13 specifies the obligations to be met by persons other than manufacturers.

Regulation 14 requires persons placing devices on the market to supply the Secretary of State with certain information about themselves and the devices.

Regulation 15 specifies, by reference to Annex VIII of the Directive, the rules in respect of custom-made devices.

Regulation 16 specifies, by reference to Annex VIII of the Directive, the rules relating to devices intended for clinical investigation.

Regulation 17 provides for the approval of the notified bodies which are to carry out tasks as part of a procedure mentioned in regulation 7, 8, 9 or 10. Regulation 17 also requires that such bodies must meet conditions specified in Annex XI of the Directive.

Regulation 18 creates offences.

Regulation 19 provides that the Regulations are to be regarded for the purposes of enforcement as safety regulations and safety provisions as defined in the Consumer Protection Act 1987, although they are made partly in exercise of other powers.

Regulation 20 provides for the setting up of a centralised system of records containing information on incidents occurring after devices have been placed on the market.

Regulation 21 makes provision for the fees chargeable by the notified bodies for work done under the Regulations.

Regulation 22 contains transitional provisions.

Regulation 23 provides for the notification of decisions by the Secretary of State and the notified bodies.

Regulations 24 and 25 contain amendments required in consequence of the Regulations.

Regulation 26 contains amendments required to take account of transitional provisions affecting clinical thermometers.

Regulation 27 contains amendments required to take account of changes affecting electro-medical equipment.

A cost compliance assessment is available, copies of which have been placed in the libraries of both Houses of Parliament.

Copies of the assessment are also available from the Medical Devices Agency, Room 620, 14 Russell Square, London WC1B 5EP.