EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 and the Medical Devices Regulations 2002.

The Medical Devices (Consultation Requirements) (Fees) Regulations 1995 prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC concerning medical devices(**1**). Regulation 2 of these Regulations amends the 1995 Regulations by increasing the amounts of the fees specified in regulations 3 and 3A of those Regulations (overall average increase of 6%).

The Medical Devices Regulations 2002 contain the legislative measures necessary for the implementation of the European Community scheme for regulating the placing on the market and putting into service of medical devices, set out in Council Directive 90/385/EEC on the approximation of the laws of Member States relating to active implantable medical devices (**2**), Council Directive 93/42/EEC concerning medical devices and Council Directive 98/79/EC on *in vitro* diagnostic devices(**3**).Regulation 3 of these Regulations amends regulations 54 to 56 of the Medical Devices Regulations 2002, which provide for the fees payable in connection with the designation etc of UK notified bodies and EC conformity assessment bodies and the fees payable in relation to clinical investigation notices. The overall increase in fees is 6%.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ and copies have been placed in the libraries of both Houses of Parliament.

(**1**) OJNo. L169, 12.7.93, p.1 to which amendments have been made by Directive 2000/70/EC of the European Parliament and of the Council, OJ No. L 313, 13.12.2000, p.22, Directive 2001/104/EC of the European Parliament and of the Council, OJ No. L 6, 10.1.2002, p. 50 and Directive 2007/47/EC of the European Parliament and of the Council , OJ No L 247, 21.9.2007, p.21.
(**2**) OJ No. L189, 20.7.90, p.17 to which amendments have been made by Council Directive 93/68/EEC, OJ No. L 220, 30.8.1993, p.1 and Directive 2007/47/EC.
(**3**) OJ No. L331, 7.12.98, p.1.