
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations (“the Regulations”) prescribe the fees payable in connection with the services provided by the Department of Health in pursuance of the Secretary of State’s functions under Council Directives [90/385/EEC](#) on the approximation of the laws of member States relating to active implantable medical devices and [93/42/EEC](#) concerning medical devices.

The main provisions are as follows.

Regulation 3 provides that, subject to the provisions of the Regulations, the fee payable in connection with the services provided by the Department of Health are as specified in the Schedule to the Regulations.

Regulation 4 provides, subject to the exception in regulation 4(2), that no fee shall be payable in connection with a notice by a manufacturer of his intention to make a device available for clinical investigation if he has previously given a notice in connection with that device.

Regulation 4(2) provides that a fee shall be payable where the investigation plan accompanying the notice differs from the plan submitted with the immediately preceding notice in any of the ways specified.

Regulation 5 provides that fees 1(a), 1(b) and 2(a) to 2(d) shall accompany the respective notice, application for designation, or request for extension and for any other fee to be payable within one month of the Secretary of State’s written request for payment.

Regulation 6 provides for reduced fees to be payable on notices or applications for designation which are withdrawn within a certain period and for the difference between the reduced fee and the fee otherwise payable to be repaid by the Secretary of State.

A compliance cost 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, 11th Floor South, Hannibal House, Elephant and Castle, London SE1 6TQ.