STATUTORY INSTRUMENTS

1995 No. 2487

The Medical Devices Fees Regulations 1995

Interpretation

2. In these Regulations, unless the context otherwise requires—

(a) "the 1990 Directive" means Council Directive 90/385/EEC on the approximation of the laws of Member States relating to active implantable medical devices(**1**) as amended by the 1993 Directive and by Council Directive 93/68/EEC(**2**);

"the 1992 Regulations" means the Active Implantable Medical Devices Regulations 1992(**3**);

"the 1993 Directive" means Council Directive 93/42/EEC concerning medical devices(**4**);

"the 1994 Regulations" means the Medical Devices Regulations 1994(**5**);

"active implantable device" means a device as defined in the 1992 Regulations;

"application for designation" means an application for designation as a notified body under regulation 8(1) of the 1992 Regulations or regulation 17(1) of the 1994 Regulations;

"device" means a device as defined in the 1994 Regulations;

"Group A device" means a Class I device, a Class IIa device or a Class IIb device other than an implantable or long term invasive device;

"Group B device" means a Class IIb implantable or long term invasive device, a Class III device or an active implantable device;

"half day" means a period of three and a half hours;

"material extension" means an extension—

(a) to add or substitute tasks relating to:

(i) active implantable devices in addition to or in substitution of tasks relating to other devices, or

(ii) devices which are materially different in technology from devices in connection with which they have already been designated tasks having regard to the risk they pose to the health and safety of patients and the skills needed to assess those risks,

(b) to add or substitute tasks relating to the procedures specified in Annex 3 or 4 of the 1990 Directive or Annex III or IV of the 1993 Directive in addition to or in substitution of tasks relating to procedures specified in Annex 2 or 5 of the 1990 Directive or Annex II, V or VI of the 1993 Directive or vice versa,

(**1**) OJNo. L189, 20.7.90, p. 17; implemented by S.I.1992/3146, amended by S.I. 1995/1671
(**2**) OJ No. L 220, 30.8.93, p. 1.
(**3**) S.I. 1992/3146; amended by S.I. 1995/1671
(**4**) OJ No. L169, 12.7.93, p. 1; implemented by S.I. 1994/3017.
(**5**) S.I. 1994/3017.

(c) to add or substitute tasks in relation to the procedures specified in Annex 3 of the 1990 Directive or Annex III of the 1993 Directive in addition to or in substitution of tasks relating to the procedures specified in Annex 4 of the 1990 Directive or Annex IV of the 1993 Directive,

(d) to add or substitute tasks relating to the procedures specified in Annex 2 of the 1990 Directive or Annex II of the 1993 Directive in addition to or in substitution of tasks relating to the procedures specified in Annex 5 of the 1990 Directive or Annex V or VI of the 1993 Directive, or

(e) to add or substitute tasks relating to the procedures specified in Annex V of the 1993 Directive in addition to or in substitution of tasks specified in Annex VI of the 1993 Directive;

"notice" means notice to the Secretary of State under regulation 7(1) of the 1992 Regulations or regulation 16(1) of the 1994 Regulations of the making available of a device for clinical investigation;

"the Table" means the table set out in the Schedule to these Regulations;

(b) any other words and expressions used both in these Regulations and in the 1990 Directive or the 1993 Directive shall bear the same meaning in these Regulations as they bear in the relevant Directive;

(c) a device shall be classified as belonging to Class I to III or as implantable or long term invasive in accordance with the criteria in Annex IX of the 1993 Directive;

(d) fee described by reference to a number and letter means a fee provided for in column (3) of the Table in relation to that number and letter in column (1) of the Table.