STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VI

Fees charged by the Secretary of State

Interpretation of Part VI

52.—(1) In this Part, unless the context otherwise requires—

"Group A device" means a Class I medical device, a Class IIa medical device, or a Class IIb medical device which is neither an implantable device nor a long term invasive medical device;

"Group B device" means a Class IIb medical device which is either an implantable medical device or a long term invasive medical device, or a Class III medical device, or an active implantable medical device; and "half day" means a period of three and a half hours.

(2) For the purposes of this Part, medical devices are classified as being implantable or long term invasive medical devices in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42, and in the event of a dispute over the classification of a device, the Secretary of State shall determine the classification of the device in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42.