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STATUTORY INSTRUMENTS

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**2002 No. 618**

**The Medical Devices Regulations 2002**

**PART VI**

*Fees charged by the Secretary of State*

**Fees payable in connection with the designation etc. of EC conformity assessment bodies**

**55.**—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 48 as an EC CAB shall, in connection with that application for designation, pay to the Secretary of State—

- (a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of £650; or
- (b) in all other cases, a fee of £2,600.

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 48(4) of the tasks that the body may carry out shall, in connection with that application for a variation, pay to the Secretary of State a fee of £1,300.

(3) Where, pursuant to regulation 48(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, the body shall pay to the Secretary of State—

- (a) in respect of an initial inspection pursuant to regulation 48(7)(a), a fee of £3,200, plus—
  - (i) an amount for time spent by a member of staff undertaking a site visit at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate, for the time spent travelling to and from the site, of £51.39 per hour,
  - (ii) the actual costs of travel, accommodation and subsistence, and
  - (iii) out of pocket expenses;
- (b) in respect of any other inspection pursuant to regulation 48(7)(a), a fee of £2,600, plus—
  - (i) an amount for time spent by a member of staff undertaking a site visit at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate, for the time spent travelling to and from the site, of £51.39 per hour,
  - (ii) the actual costs of travel, accommodation and subsistence, and
  - (iii) out of pocket expenses; and
- (c) in respect of an inspection pursuant to regulation 48(7)(b), a fee of £2,600, plus—
  - (i) an amount for time spent by a member of staff undertaking a site visit at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate, for the time spent travelling to and from the site, of £51.39 per hour,

- (ii) the actual costs of travel, accommodation and subsistence, and
  - (iii) out of pocket expenses.
- (4) A fee under this regulation—
  - (a) in connection with an application for designation under regulation 48(1) or a variation under regulation 48(4)—
    - (i) shall be payable when the application to the Secretary of State is made, and
    - (ii) shall accompany the application when it is made;
  - (b) in connection with an inspection pursuant to regulation 48(7), shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.