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STATUTORY INSTRUMENTS

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**2002 No. 618**

**The Medical Devices Regulations 2002**

**PART V**

*Notified Bodies, Conformity Assessment Bodies and Marking of Products*

**Fees charged by UK notified bodies and EC conformity assessment bodies**

**49.**—(1) A UK notified body or EC CAB may charge a fee in accordance with paragraphs (2), (3) and (4) for anything done in, or in connection with—

- (a) in the case of a UK notified body, performing the functions of a notified body or an importing Party under the Medical Devices Directives or the Mutual Recognition Agreements in respect of a conformity assessment procedure set out in the Medical Devices Directives; and
- (b) in the case of an EC CAB, performing the functions of an EC CAB arising out of the Mutual Recognition Agreements in respect of a conformity assessment procedure for a medical device.

(2) Except as provided for by paragraph (3), the fee charged in respect of anything done shall not exceed an amount which reasonably represents the cost incurred, or to be incurred, in doing it.

(3) Where the UK notified body or EC CAB charging the fee is a body the activities of which are carried on for profit, the fee may include an amount representing a profit which is reasonable in the circumstances, having regard to—

- (a) the character and extent of the work done or to be done by the notified body; and
- (b) the commercial rate normally charged in respect of profit for that work or similar work.

(4) The UK notified body or EC CAB may require payment of the fee, or a reasonable estimate of the fee, in advance of carrying out the work in respect of which the fee is payable and as a condition of doing that work.