STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

UK notified bodies and the conformity assessment procedures for general medical devices

18.—(1) A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

(a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device;

(b) take account of any relevant information relating to the characteristics and performance of that device, including in particular the results of any relevant tests and verification relating to that device already carried out under the laws or administrative provisions in force before 1st January 1995 in any EEA State; and

(c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annex II to IV.

(2) Where a UK notified body takes a decision in accordance with Annex II or III, they shall specify the period of validity of the decision, which initially shall be for a period of not more than five years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to five years, each such period commencing on the expiry of the previous period.