STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART V

Notified Bodies, Conformity Assessment Bodies and Marking of Products

Products incorrectly marked with a notified body or conformity assessment body number

50.—(1) No person shall—

(a) affix a notified body or conformity assessment body number to a medical device if that body has not carried out an assessment in respect of that device for that person;

(b) supply a medical device (if that supply is also a placing on the market, or if that supply is of a device which has been placed on the market) which has affixed to it a notified body or conformity assessment body number if that body—

(i) has not carried out an assessment in respect of that device, or has not carried out that assessment for the person responsible for placing the device on the market, or

(ii) has had its designation as a notified body or conformity assessment body withdrawn.

(2) No person shall provide information comprising a notified body or conformity assessment body number on a medical device, the instructions for use for a medical device, or the sales packaging for a medical device if that device—

(a) is being or has been placed on the market; and

(b) the notified body or conformity assessment body—

(i) has not carried out an assessment in respect of that device, or has not carried out that assessment for the person responsible for placing the device on the market, or

(ii) has had its designation as a notified body or conformity assessment body withdrawn.

(3) Where the sectoral annex on medical devices in a Mutual Recognition Agreement under which a conformity assessment body was designated states that the annex does not apply to devices of a particular class or description, no person may supply a medical device of that class or description bearing the number of that conformity assessment body (if that supply is also a placing on the market or putting into service or is of a device that has been placed on the market or put into service) unless—

(a) an assessment has been carried out on that device for the person responsible for placing it on the market or putting it into service by a notified body; and

(b) the device bears the notified body number of that notified body.

(4) For the purposes of this regulation, a notified body shall be taken to have carried out an assessment in respect of a device if it has endorsed a report prepared by a third country conformity assessment body in respect of that device.