STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART III

Active Implantable Medical Devices

Determining compliance of active implantable medical devices with relevant essential requirements

23.—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) Any—

(a) determination that a relevant device complies with any of the essential requirements set out in paragraphs 1 to 5 of Annex 1; and

(b) evaluation of side effects or undesirable effects for the purposes of determining whether or not a relevant device complies with any of the essential requirements,

shall be based in particular on clinical data, the adequacy of which is based on the collation of scientific literature or the results of clinical investigations referred to in paragraph 1 of Annex 7, and any determination as to whether or not a relevant device complies with any other essential requirements may be based on such data.

(3) In the case of a relevant device which is being or has been put into service—

(a) the essential requirements specified in paragraph 14 of Annex 1 are complied with only if the particulars there specified are in English (whether or not they are also in another language and whether or not the device is for professional use); and

(b) the essential requirements specified in paragraph 13 of Annex 1, so far as they relate to instructions required for the operation of a device in paragraph 15 of Annex 1, are complied with only if—

(i) the instructions are in English or another Community language, and

(ii) if the instructions are not in English, any packaging, label or promotional literature carries a clear statement in English stating the language in which the instructions are given.

(4) A relevant device shall be treated as complying with an essential requirement if it conforms as respects that requirement to a relevant national Standard, unless there are reasonable grounds for suspecting that the device does not comply with that requirement.

(5) A custom-made device in respect of which the conditions specified in Annex 6 are satisfied and which is accompanied by the statement referred to in paragraph 1 of Annex 6 shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.

(6) A device intended for clinical investigation in respect of which—

(a) the conditions specified in Annex 7 are satisfied;

(b) notice has been given under regulation 29(1); and

(c) either—

(i) no notice has been given under regulation 29(3) within the period of 60 days there referred to, or

(ii) notice has been given under regulation 29(4),

shall be taken to comply with the relevant essential requirements unless there are reasonable grounds for suspecting that the device does not comply with those requirements.