STATUTORY INSTRUMENTS

1992 No. 3146

The Active Implantable Medical Devices Regulations 1992

Enforcement etc.

10.—(1) Notwithstanding that they are made partly in exercise of powers other than those conferred by section 11 of the 1987 Act these Regulations shall be regarded for all purposes relating to enforcement (whether by criminal proceedings or notices or otherwise) and for the purposes of section 38 of that Act (disclosure of information) as safety regulations as defined in that Act and any provision of these Regulations made under those other powers shall be regarded for those purposes as a safety provision as defined in that Act.

(2) Each weights and measures authority and each district council in Northern Ireland is relieved of its duty imposed by section 27(1) of the 1987 Act in so far as it is exercisable in relation to devices.

(3) The powers conferred by section 13 of the 1987 Act to serve prohibition notices and notices to warn are exercisable in relation to non—conforming devices as they are exercisable in relation to relevant goods which the Secretary of State considers are unsafe (as well as being exercisable in relation to such goods), and in relation to non—conforming devices Schedule 2 to the 1987 Act shall have effect as if references to goods being unsafe or safe were references to devices being or not being non—conforming devices.

(4) In paragraph (3) "non—conforming devices" means devices which, whether or not the Secretary of State considers them unsafe, he considers to be devices to which the EC mark has been wrongly applied and to be devices—

(a) which do not conform as respects a relevant essential requirement to a relevant national Standard where the device is held out as respects that essential requirement as conforming to that Standard; or

(b) where the devices are ones to which the EC mark has been applied following the EC declaration of conformity procedure, in respect of which the manufacturer or his authorised representative has failed to comply with his obligations under that procedure; or

(c) where the devices are ones to which the EC mark has been applied following the EC type —examination procedure, which do not conform to the type described in the relevant EC type—examination certificate or which conform to such a type which does not meet the relevant essential requirements.