STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VII

General, Enforcement and Miscellaneous

Enforcement etc.

61.—(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, notices or otherwise) and for the purposes of section 38 of that Act (disclosure of information) as safety regulations as defined in that Act(**1**), 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**).

(2) Except as provided by paragraph (3), each weights and measures authority in Great Britain 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 relevant devices or devices for performance evaluation, and that duty is transferred to the Secretary of State.

(3) Paragraph (2) does not relieve an authority or council of its duty in relation to devices which are consumer goods for the purposes of Part II of the 1987 Act(**3**), and accordingly but subject to paragraph (4), each weights and measures authority in Great Britain and each district council in Northern Ireland shall, concurrently with the Secretary of State, enforce these Regulations in relation to such devices.

(4) The powers of an enforcement authority to serve restriction notices under regulation 63 are only exercisable by the Secretary of State.

(5) Each authority and council referred to in paragraph (3) on whom a duty is imposed by section 27(1) of the 1987 Act to enforce the provisions of these Regulations shall give immediate notice to the Secretary of State of—

(a) any suspension notice served by it under section 14 of the 1987 Act in respect of a device to which paragraph (3) applies;

(b) any application made by it under section 16 of the 1987 Act for an order for forfeiture of any such device; and

(c) any other thing done by it in respect of such a device for the purposes of, or in connection with the operation of, sections 14 to 17 of the 1987 Act.

(6) In respect of an offence committed under section 12 of the 1987 Act relating to a contravention of these Regulations—

(a) a magistrates' court in England or Wales may try any information laid within 12 months from the time when the offence was committed;

(**1**) *See* section s 11(1) and 45(1) of that Act.
(**2**) *See* section 45(1) of that Act.
(**3**) *See* section 11(7) of that Act.

(b) a magistrates' court in Northern Ireland may hear and determine any complaint made within 12 months from the time when the offence was committed; and

(c) in Scotland, summary proceedings for the offence may be commenced at any time within 12 months from the time when the offence was committed.

(7) 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 goods considered unsafe by the Secretary of State), 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 relevant devices being or not being non-conforming devices.

(8) In paragraph (7), "non-conforming devices" means—

(a) relevant devices which, whether or not the Secretary of State considers them unsafe, are devices with or that require a CE marking which he considers to be devices—

(i) which do not conform as respects a relevant essential requirement; or

(ii) to which a CE marking has or should have been applied following a conformity assessment procedure set out in the Medical Devices Directives, and—

(aa) the manufacturer or his authorised representative has failed to comply with his obligations under that procedure, or

(bb) they do not conform to the design or type described in any certificate granted as a result of that procedure; or

(b) devices for performance evaluation which, whether or not the Secretary of State considers them unsafe, are devices in respect of which there is a failure to comply with these Regulations.