STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VII

General, Enforcement and Miscellaneous

Interpretation of Part VII

59. In this Part, unless the context otherwise requires—

"registrable device" means a device in respect of which, in accordance with the Medical Devices Directives, registration is required with the competent authorities of a Member State or (where appropriate) a State which is a Party to an Association Agreement;

"relevant device" means a device that is a "relevant device" for the purposes of Part II, III or IV.

Designation etc. of authorised representatives

60.—(1) Where these Regulations place any obligation, other than an obligation referred to in regulation 17(3), on a manufacturer of a device or his authorised representative, and the manufacturer does not have a registered place of business in the Community or (where appropriate) in a State which is a Party to an Association Agreement, no person shall—

(a) place that device on the market; or

(b) supply that device in circumstances where it has been placed on the market,

unless the manufacturer of the device has designated an authorised representative to perform that obligation, but once the manufacturer has designated an authorised representative to perform that obligation, that obligation shall be performed by the authorised representative (although in all other cases it shall be performed by the manufacturer).

(2) If the manufacturer of a registrable device does not have a registered place of business in the Community or (where appropriate) in a State which is a Party to an Association Agreement, no person shall place that device on the market or supply that device in circumstances where it has been placed on the market unless its manufacturer has designated an authorised representative as—

(a) the person responsible for marketing the device in the Community; and

(b) the person responsible for registering in respect of that device with—

(i) the Secretary of State in accordance with regulation 19 or, as the case may be, 44, or

(ii) the competent authorities of another Member State or (where appropriate) a State which is a Party to an Association Agreement.

(3) Where a manufacturer of a registrable device, or of a relevant device that is not registrable, has designated an authorised representative as the person responsible for marketing the device within the Community, that authorised representative—

(a) may be proceeded against as a person placing the device on the market for the purposes of these Regulations;

(b) in relation to any supply of the device to a person within the United Kingdom after it has been placed on the market, may be proceeded against as a person supplying the device after it has been placed on the market, unless that supply is due to an act of another person established in the Community or in a State which is a Party to an Association Agreement.

(4) If a person claims or purports to act as an authorised representative of a manufacturer of a device, the Secretary of State may, for the purposes of enabling the Secretary of State to exercise his functions under these Regulations, require that person to furnish the Secretary of State with sufficient evidence that he is an authorised representative of the manufacturer.

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 [M1], 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 [M2].

(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 [M3], 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;

(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.

Marginal Citations

M1 *See* section s 11(1) and 45(1) of that Act.

M2 *See* section 45(1) of that Act.

M3 *See* section 11(7) of that Act.

Compliance notices

62.—(1) Except in the case of a device which in the opinion of an enforcement authority is likely to compromise the health or safety of any person, where an enforcement authority has reasonable grounds for suspecting that a relevant device or a device for performance evaluation is a device in respect of which there is a failure to comply with these Regulations, that authority may serve upon the manufacturer or his authorised representative a notice—

(a) specifying the description of the device to which the notice relates;

(b) stating that the enforcement authority suspects the device is a device in respect of which there is failure to comply with these Regulations and the reasons for that suspicion;

(c) specifying the relevant provision of these Regulations and, where applicable, any relevant provision of the Medical Devices Directives;

(d) requiring the person on whom the notice is served—

(i) to secure that any device to which the notice relates conforms as regards the specified provision within such period as may be specified in the notice, or

(ii) to provide evidence within that period to the satisfaction of the enforcement authority that all the provisions of these Regulations have been complied with in so far as they relate to that device; and

(e) warning the person on whom the notice is served that unless the requirements of sub—paragraph (d) are met, further action may be taken under these Regulations or the 1987 Act in respect of that device or any device of the same type supplied by that person.

(2) Where an enforcement authority serves a notice referred to in paragraph (1), section 14, 16 or 17 of the 1987 Act shall not be applied as respects any device to which the notice relates until the period referred to in paragraph (1)(d) has expired and unless, in relation to the alleged failure

to comply with these Regulations, at the expiry of that period the person on whom the notice was served has failed to comply with its requirements.

(3) The notice referred to in paragraph (1) may include directions as to the measures to be taken by the person on whom the notice is served to secure compliance with the provisions of these Regulations, including different ways of securing compliance, and any such directions are requirements of the notice for the purposes of paragraph (2).

Restriction notices

63.—(1) Subject to paragraph (2), where an enforcement authority is of the opinion that it is necessary to restrict the availability of—

(a) a particular medical device, a particular accessory to such a device or a particular device for performance evaluation; or

(b) medical devices, accessories to such devices or devices for performance evaluation of a particular class or description,

in order to protect the health or safety of any individual or of individuals of any class or description, they may serve on any person a notice ("a restriction notice") including such directions restricting the availability of that device or those devices as appear to them to be necessary in order to protect the health or safety of that individual or individuals of that class or description.

(2) Paragraph (1) shall not apply to active implantable medical devices or to accessories to such devices.

(3) The enforcement authority responsible for serving a restriction notice may, in appropriate circumstances, withdraw the notice.

(4) A direction in a restriction notice that has not been withdrawn by an enforcement authority or set aside by an order of a court or a sheriff is a safety provision for the purposes of sections 14 to 17 of the 1987 Act.

(5) Where, in the course of or as a result of enforcement action in relation to a suspected contravention of a direction in a restriction notice, an application has been made to a magistrates' court or a sheriff—

(a) under section 15 of the 1987 Act (appeals against suspension notices), the court or the sheriff may make an order setting aside the restriction notice as well as any suspension notice served in respect of the suspected contravention of the direction;

(b) under section 16 or 17 of the 1987 Act (which relate to forfeiture of goods), the court or the sheriff may make an order setting aside the restriction notice,

if the court or the sheriff is satisfied that the restriction notice should not have been served or should be withdrawn.

(6) Any person aggrieved by an order made under paragraph (5), or by a decision not to make such an order, may appeal against that order or decision, and that appeal shall be treated in the same way as any other appeal that has been or could be made against any other decision or order of the court in the proceedings under section 15, 16 or 17 of the 1987 Act which led to the decision or order relating to the restriction notice being made.

Notification of decisions etc.

64.—(1) Any decision taken by a UK notified body, the Secretary of State or any other enforcement authority pursuant to these Regulations to withdraw a device from the market, or to prevent or restrict a device being placed on the market, put into service or made available, shall be notified without delay to the person responsible for marketing the device, placing it on the market, putting it into service or making it available, and that person shall be informed—

(a) of the grounds on which the decision is based;

(b) of the legal remedies available to that person and of any time limits which apply to their exercise; and

(c) if the applicant was not entitled under the 1987 Act to make representations in respect of the decision, that the decision maker will, on request, review the decision and in the course of so doing will give him or his authorised representative an opportunity to make representations in respect of the decision.

(2) Except in cases where urgent action is justified (in particular by public health requirements), if a UK notified body, the Secretary of State or any other enforcement authority is considering making a decision referred to in paragraph (1), they or he shall give the manufacturer or his authorised representative an opportunity to make representations to them or him before the decision is taken.

Centralised systems of records etc.

65. The Secretary of State shall perform, as respects the United Kingdom, the functions of the Member State under article 8 of Directive 90/385, article 10 of Directive 93/42 and article 11(1) to (3) of Directive 98/79.

Revocations

66. The following provisions are hereby revoked—

(a) the Active Implantable Medical Devices Regulations 1992 [M4];

(b) the Medical Devices Regulations 1994 [M5];

(c) the Active Implantable Medical Devices (Amendment and Transitional Provisions) Regulations 1995 [M6];

(d) the Medical Devices Fees Regulations 1995 [M7];

(e) the Medical Devices Fees (Amendment) Regulations 1997 [M8];

(f) the*In Vitro* Diagnostic Medical Devices Regulations 2000 [M9]; and

(g) regulations 6 and 13 of the Medicines (Codification Amendments Etc.) Regulations 2002 [M10].

Marginal Citations

M4 S.I. 1992/3146.
M5 S.I. 1994/3017.
M6 S.I. 1995/1671.
M7 S.I. 1995/2487.
M8 S.I. 1997/694.
M9 S.I. 2000/1315.
M10 S.I. 2002/236.

Status:
Point in time view as at 13/06/2002.

Changes to legislation:
The Medical Devices Regulations 2002, PART VII is up to date with all changes known to be in force on or before 31 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.