
STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VII

General, Enforcement and Miscellaneous

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(4) A direction in a restriction notice that has not been withdrawn by an enforcement authority or set aside by an order of a court or a sheriff is a safety provision for the purposes of sections 14 to 17 of the 1987 Act.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if the court or the sheriff is satisfied that the restriction notice should not have been served or should be withdrawn.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