

Section 41K

**Part 4-9—Public notification and recovery of
medical devices**

41K What this Part is about

The Secretary can require action to recover medical devices, or to inform the public about medical devices, that do not comply with requirements or cannot lawfully be supplied.

41KA Public notification and recovery of medical devices

- (1) The Secretary may, in writing, impose requirements, relating to a kind of medical device, on a person if:
- (a) any of the circumstances referred to in the second column of an item in the following table occur in relation to the kind of device; and
 - (b) the person is referred to in the third column of that item of the table.

Circumstances in which requirements may be imposed		
Item	Circumstance relating to a kind of medical device	Person subject to requirements
1.	It is supplied while it is included in the Register, but medical devices of that kind do not comply with the essential principles	The person in relation to whom it is included in the Register
2.	It is supplied while it is included in the Register, but the conformity assessment procedures have not been applied to medical devices of that kind	The person in relation to whom it is included in the Register

Chapter 4 Medical devices

Part 4-9 Public notification and recovery of medical devices

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Circumstances in which requirements may be imposed		
Item	Circumstance relating to a kind of medical device	Person subject to requirements
3.	It is supplied while: (a) medical devices of that kind are exempt devices; or (b) there is an approval under section 41HB relating to devices of that kind; or (c) there is an authority under section 41HC relating to devices of that kind; but medical devices of that kind do not comply with the essential principles	The person supplying the kind of medical device
4.	It is supplied while: (a) medical devices of that kind are exempt devices; or (b) there is an approval under section 41HB relating to devices of that kind; or (c) there is an authority under section 41HC relating to devices of that kind; but the conformity assessment procedures have not been applied to medical devices of that kind	The person supplying the kind of medical device
5.	It is supplied while: (a) it is not included in the Register; and (aa) it is not covered by an exemption in force under section 41GS; and (b) it is not an exempt device; and (c) there is not an approval under section 41HB relating to devices of that kind; and (d) there is not an authority under section 41HC relating to devices of that kind.	The person supplying the kind of medical device
5A.	It is supplied while it is covered by an exemption in force under section 41GS, and the Secretary is satisfied that it is not fit to be used for its intended purpose	The person supplying the kind of medical device

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Circumstances in which requirements may be imposed

Item	Circumstance relating to a kind of medical device	Person subject to requirements
5B.	It is supplied while it is included in the Register, but it appears to the Secretary that the quality, safety or performance of medical devices of that kind is unacceptable	The person in relation to whom the kind of medical device is included in the Register
6.	It has been suspended from the Register	The person in relation to whom it was included in the Register
7.	Its entry has been cancelled from the Register	The person in relation to whom it was included in the Register

- (2) The requirements may be one or both of the following:
- (a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recover medical devices of that kind that have been distributed;
 - (b) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, to the effect that the circumstances referred to in paragraph (1)(a) have occurred in relation to medical devices of that kind.
- (3) If the circumstances referred to in paragraph (1)(a) apply only to some medical devices of that kind, the Secretary may limit the imposition of the requirements to the medical devices of that kind to which those circumstances apply.
- (4) A requirement to recover medical devices under this section does not apply to a medical device that cannot be recovered because it has been administered to, or applied in the treatment of, a person.

41KB Publication of requirements

The Secretary must cause to be published in the *Gazette*, as soon as practicable after imposing a requirement under section 41KA, a notice setting out particulars of the requirement.

