STATUTORY INSTRUMENTS

1994 No. 3119

The Medical Devices (Consequential Amendments—Medicines) Regulations 1994

Amendment of the Medicines Act 1968

2. In section 130 of the Medicines Act 1968(1) (meaning of "medicinal product" and related expressions)—

- (a) in subsection 5(b) for the words "where the medication has a curative function which is not limited to sterilising the dressing" there shall be substituted the words "within subsection (5A) below";
- (b) after subsection (5) the following subsection shall be inserted—

"(5A) Medicated dressings are within this subsection (and accordingly are not excluded from the definition of "medicinal product" by subsection (5)(b) above) if—

- (a) their medication has a curative function which is not limited to sterilising the dressing; and
- (b) they are not dressings of a kind to which the requirements of Article 2 of Council Directive 93/42/EEC(2) (placing medical devices on the market and putting them into service) apply or would apply but for Article 4 (devices intended for special purposes) or 22 (transitional provisions) of that Directive.".

^{(1) 1968} c. 67.

⁽²⁾ O.J. No. L 169 12.7.93 p.1.