## 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.".

<sup>(1) 1968</sup> c. 67.

<sup>(2)</sup> O.J. No. L 169 12.7.93 p.1.