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STATUTORY INSTRUMENTS

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**2008 No. 2936**

**The Medical Devices (Amendment) Regulations 2008**

**Amendment of regulation 21 of the principal Regulations**

**12.** In regulation 21 of the principal Regulations (scope of Part III)—

- (a) the existing paragraph shall be numbered (1); and
- (b) after paragraph 1 add—

“(2) Where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to Directive 90/385.

(3) Where an active implantable medical device is intended to administer a medicinal product, that device shall be governed by Directive 90/385 without prejudice to the provisions of Directive [2001/83/EC](#).”