STATUTORY INSTRUMENTS

2008 No. 2936

The Medical Devices (Amendment) Regulations 2008

Amendment of regulation 16 of the principal Regulations

9. In regulation 16 of the principal Regulations (procedures for general medical devices for clinical investigations) —

(a) in paragraph (1)(a)—

"for "Sections 1 and 2" substitute "Sections 1 and 2.2"; and

(b) after paragraph (10) add—

"(11) The manufacturer, or their single authorised representative, shall—

(a) notify the Secretary of State of the end of the clinical investigation; and

(b) provide justification where premature termination has resulted.".