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STATUTORY INSTRUMENTS

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**2023 No. 377**

**The Medical Devices and Blood Safety and  
Quality (Fees Amendment) Regulations 2023**

**PART 2**

**Amendment of the Medical Devices Regulations 2002**

**Amendment of regulation 29 in relation to England, Scotland and Wales (procedures for active implantable medical devices for clinical investigations)**

**6.** After regulation 29(1)(1), insert—

“(1A) A manufacturer or their UK responsible person may request a meeting with the Secretary of State in advance of giving notice in writing to the Secretary of State pursuant to paragraph (1) in order to—

- (a) obtain advice on regulatory requirements relating to an intended clinical investigation; or
- (b) obtain a statistical review in relation to an intended clinical investigation.”.