EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations contain the legislative measures necessary for the implementation of three European Community Directives: Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, as amended; Council Directive 93/42/EEC concerning medical devices, as amended; and Directive 98/79/EC of the European Parliament and of the Council on*in vitro* diagnostic medical devices ("the Medical Devices Directives"). They also contain the legislative measures necessary for the implementation, in relation to medical devices, of the agreements on mutual recognition between the European Community and Australia, New Zealand, Canada and the United States of America—and of the Association Agreement between the European Communities, and their Member States, and Hungary.

Part I contains introductory provisions. These include an interpretation provision (regulation 2), and provisions both limiting the scope of the application of the Regulations so that they only apply to products covered by the Medical Devices Directives (regulation 3) and delaying the application of provisions of the Regulations in relation to specific categories of medical devices, to take account of the transitional arrangements in the Medical Devices Directives (regulation 4).

Part II deals with the marketing of medical devices generally, but not with active implantable medical devices or*in vitro* diagnostic medical devices. Medical devices covered by this Part must generally meet the essential requirements set out in Annex I to Directive 93/42/EEC (regulations 8 and 9), and must be CE-marked according to the conformity assessment procedures set out in that Directive (regulations 10 and 13). There are exemptions for certain products (regulation 12), and special arrangements for products covered by more than one European Community Directive (regulation 11). There are also specific arrangements for systems and procedure packs, custom-made devices and devices intended for clinical investigations (regulations 14 to 16). Arising out of the conformity assessment procedures, there are specific obligations placed on manufacturers of devices or their authorised representatives (regulation 17), and on the notified bodies involved in carrying out assessments in respect of devices (regulation 18). Manufacturers of certain medical devices, or their authorised representatives, must register with the Secretary of State (regulation 19).

Part III deals with active implantable medical devices. Again, these can only be marketed if they meet specified essential requirements, set out in Directive 90/385/EEC (regulations 22 and 23), and are assessed under conformity assessment procedures (regulations 24 and 27). There are special arrangements for devices that come under more than one European Community Directive (regulation 25), and some exemptions from the scheme (regulation 26). Again, there are different procedures for custom-made devices and devices for clinical investigation (regulations 28 and 29). Specific obligations are imposed on manufacturers or their authorised representatives (regulation 30), and on notified bodies carrying out assessments in respect of the devices (regulation 31).

Part IV deals with*in vitro* diagnostic medical devices. These also must conform to the essential requirements set out in Directive 98/79/EC (regulations 33 and 34), and must be CE-marked according to one of the conformity assessment procedures set out in the Directive (regulations 36 and 40). There are again exemptions (regulation 39), and special arrangements for products caught by more than one European Community Directive (regulation 37). There are also special arrangements for devices for performance evaluation (regulation 43). Manufacturers or their authorised representatives have specific obligations relating to the conformity assessment procedures (regulation 41), and generally have to register (regulation 44). Notified bodies also have specific obligations relating to the conformity assessment procedures (regulation 42).

Part V contains general provisions relating to the designation of notified bodies within the United Kingdom (regulation 45). Companies may apply to any European Community notified body or third country conformity assessment body (the equivalent body under a Mutual Recognition Agreement) to carry out tasks under a conformity assessment procedure, if the task is within the framework of tasks that the body is designated to carry out (regulation 46). There are also provisions for designating conformity assessment bodies to carry out conformity assessment work for other Parties to Mutual Recognition Agreements (regulation 48). This Part also contains prohibitions on marking products with CE marks or with notified body or conformity assessment body numbers if they are not entitled to bear those markings (regulations 50 and 51).
Part VI sets out the fees charged by the Secretary of State in relation to work done pursuant to the Regulations. These include charges in connection with the registration of devices and changes to registration details (regulation 53), charges to UK notified bodies and EC Conformity Assessment Bodies (regulations 54 and 55), and fees payable in connection with clinical investigation notices (regulation 56). There are also arrangements for unpaid fees, waivers, reductions and refunds (regulations 57 and 58).
Part VII includes general matters, including the provisions relating to designation of authorised representatives and enforcement (regulations 60 to 64), and requirements to keep a centralised system of records (regulation 65). This Part also contains revocations of provisions that are superseded as a result of the coming into force of these Regulations (regulation 66).
A Regulatory Impact Appraisal and a Transposition Note in relation to the implementation of Directives 2000/70/EC and 2001/104/EC (the two most recent Directives amending Council Directive 93/42/EEC), have been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medical Devices Agency, Hannibal House, Elephant and Castle, London SE1 6TQ.

Status:
Point in time view as at 01/04/2023.

Changes to legislation:
The Medical Devices Regulations 2002 is up to date with all changes known to be in force on or before 24 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.