STATUTORY INSTRUMENTS

2002 No. 618

CONSUMER PROTECTION

The Medical Devices Regulations 2002

Made---20th May 2002Laid before Parliament21st May 2002Coming into force13th June 2002

THE MEDICAL DEVICES REGULATIONS 2002

PART I

Introductory Provisions Relating to all Medical Devices

- 1. Citation and commencement
- 2. Interpretation
- 3. Scope of these Regulations
- 4. Transitional provisions

PART II

General Medical Devices

- 5. Interpretation of Part II
- 6. Scope of Part II
- 7. Classification of general medical devices
- 8. Essential requirements for general medical devices
- 9. Determining compliance of general medical devices with relevant essential requirements
- 10. CE marking of general medical devices
- 11. CE marking of general medical devices that come within the scope of more than one Directive
- 12. Exemptions from regulations 8 and 10
- 13. Procedures for affixing a CE marking to general medical devices
- 14. Procedures for systems and procedure packs, and for devices to be sterilised before use
- 15. Procedures for custom-made general medical devices
- 16. Procedures for general medical devices for clinical investigations
- Manufacturers etc. and conformity assessment procedures for general medical devices

- 18. UK notified bodies and the conformity assessment procedures for general medical devices
- 19. Registration of persons placing general medical devices on the market

PART III

Active Implantable Medical Devices

- 20. Interpretation of Part III
- 21. Scope of Part III
- 22. Essential requirements for active implantable medical devices
- 23. Determining compliance of active implantable medical devices with relevant essential requirements
- 24. CE marking of active implantable medical devices
- 25. CE marking of active implantable medical devices that come within the scope of more than one Directive
- 26. Exemptions from regulations 22 and 24
- 27. Procedures for affixing a CE marking to active implantable medical devices
- 28. Procedures for custom-made active implantable medical devices
- 29. Procedures for active implantable medical devices for clinical investigations
- 30. Manufacturers etc. and conformity assessment procedures for active implantable medical devices
- 31. UK notified bodies and the conformity assessment procedures for active implantable medical devices

PART IV

In Vitro Diagnostic Medical Devices

- 32. Interpretation of Part IV
- 33. Scope of Part IV
- 34. Essential requirements for *in vitro* diagnostic medical devices
- 35. Determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements
- 36. CE marking of *in vitro* diagnostic medical devices
- 37. CE marking of *in vitro* diagnostic medical devices that come within the scope of more than one Directive
- 38. *In vitro* diagnostic medical devices not ready for use
- 39. Exemptions from regulations 34, 36 and 38
- 40. Procedures for affixing a CE marking to *in vitro* diagnostic medical devices
- 41. Manufacturers etc. and conformity assessment procedures for *in vitro* diagnostic medical devices
- 42. UK notified bodies and the conformity assessment procedures for *in vitro* diagnostic medical devices
- 43. Devices for performance evaluation
- 44. Registration of manufacturers etc. of *in vitro* diagnostic medical devices and devices for performance evaluation

PART V

Notified Bodies, Conformity Assessment Bodies and Marking of Products

- 45. Designation etc. of UK notified bodies
- 46. Choice of notified bodies and conformity assessment bodies
- 47. General matters relating to UK notified bodies

- 48. Designation etc. of EC conformity assessment bodies
- 49. Fees charged by UK notified bodies and EC conformity assessment bodies
- 50. Products incorrectly marked with a notified body or conformity assessment body number
- 51. Products incorrectly marked with a CE marking

PART VI

Fees charged by the Secretary of State

- 52. Interpretation of Part VI
- 53. Fees in connection with the registration of devices and changes to registration details
- 54. Fees payable in connection with the designation etc. of UK notified bodies
- 55. Fees payable in connection with the designation etc. of EC conformity assessment bodies
- 56. Fees payable in relation to clinical investigation notices
- 57. Unpaid fees
- 58. Waivers, reductions and refunds

PART VII

General, Enforcement and Miscellaneous

- 59. Interpretation of Part VII
- 60. Designation etc. of authorised representatives
- 61. Enforcement etc.
- 62. Compliance notices
- 63. Restriction notices
- 64. Notification of decisions etc.
- 65. Centralised systems of records etc.
- 66. Revocations Signature

SCHEDULE 1 — ASSOCIATION AGREEMENTS

1. The Protocol to the Europe Agreement establishing an Association between...

SCHEDULE 2 — MUTUAL RECOGNITION AGREEMENTS

- 1. The agreement on mutual recognition in relation to conformity assessment...
- 2. The agreement on mutual recognition in relation to conformity assessment...
- 3. The agreement on mutual recognition between the European Community
- 4. The agreement on mutual recognition between the European Community and...

Explanatory Note