#### STATUTORY INSTRUMENTS

### 1994 No. 3017

# **CONSUMER PROTECTION**

## The Medical Devices Regulations 1994

Made - - - 28th November 1994

Laid before Parliament 30th November 1994

Coming into force

for the purposes of

regulation 17 21st December 1994

for all other purposes 1st January 1995

### THE MEDICAL DEVICES REGULATIONS 1994

- 1. Citation and commencement
- 2. Interpretation
- 3. Application of Regulations
- 4. Classification of devices
- 5. Essential requirements for devices
- 6. CE marking
- 7. Procedure for affixing CE marking for Class I devices
- 8. Procedure for affixing CE marking for Class IIa devices
- 9. Procedure for affixing CE marking for Class IIb devices
- 10. Procedure for affixing CE marking for Class III devices
- 11. Procedure for systems and procedure packs, and devices to be sterilised before use
- 12. General provisions relating to conformity assessment procedures
- 13. Obligations of persons other than manufacturers
- 14. Registration of persons placing devices on the market
- 15. Custom-made devices
- 16. Clinical investigations
- 17. Notified bodies
- 18. Prohibition on supply etc.
- 19. Enforcement etc.
- 20. Centralised system of records etc.
- 21. Fees
- 22. Transitional provisions
- 23. Notification of decisions etc.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

- 24. Amendment of Schedule 1 to the Provision and Use of Work Equipment Regulations 1992
- 25. Substitution for Schedule 1 to the Personal Protective Equipment at Work Regulations 1992
- 26. Amendment of the Clinical Thermometers (EEC Requirements) Regulations 1993
- Amendment of the Electro-medical Equipment (EEC Requirements)
  Regulations 1988
  Signature
  Explanatory Note