
STATUTORY INSTRUMENTS

1992 No. 3146

CONSUMER PROTECTION

The Active Implantable Medical Devices Regulations 1992

Made - - - - 10th December 1992

Laid before Parliament 11th December 1992

Coming into force 1st January 1993

**THE ACTIVE IMPLANTABLE MEDICAL
DEVICES REGULATIONS 1992**

1. Citation and commencement
 2. Interpretation
 3. Essential requirements for devices
 4. EC mark
 5. Procedure for affixing EC mark
 6. Custom—made devices
 7. Clinical investigations
 8. Notified bodies
 9. Prohibition on supply etc.
 10. Enforcement etc.
 11. Transitional provision
 12. Notification of decisions etc.
- Signature

SCHEDULES

- 1 — EC mark
- 2 — Essential requirements for active implantable medical devices (corresponding to Annex 1 of the Directive)
- 3 — Evaluation etc. of clinical data (corresponding to Annex 7 of the Directive)
- 4 — Conditions relating to devices for special purposes (corresponding to Annex 6 of the Directive)

Status: This is the original version (as it was originally made).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

- 5 — EC declaration of conformity procedure (corresponding to Annex 2 of the Directive) —
 - Part I— — Quality system
 - Part II— — Surveillance
- 6 — EC type—examination procedure (corresponding to Annex 3 of the Directive)
- 7 — EC verification procedure (corresponding to Annex 4 of the Directive)
- 8 — EC declaration of conformity to type procedure (corresponding to Annex 5 of the Directive) —
 - Part I— — Quality system
 - Part II— — Surveillance
- 9 — Notified bodies — condition

Explanatory Note