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STATUTORY INSTRUMENTS

2002 No. 618

CONSUMER PROTECTION

The Medical Devices Regulations 2002

<i>Made</i>	- - - -	<i>20th May 2002</i>
<i>Laid before Parliament</i>		<i>21st May 2002</i>
<i>Coming into force</i>		<i>13th June 2002</i>

THE MEDICAL DEVICES REGULATIONS 2002

PART I

Introductory Provisions Relating to all Medical Devices

1. Citation and commencement
- 1ZA Expiry of certain provisions in these Regulations
 - 1A Schedules
 2. Interpretation
 - 2A Medical devices which are qualifying Northern Ireland goods
 3. Scope of these Regulations
- 3ZA Revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
 - 3A Designated standard
 - 3B Confidentiality
 4. Transitional provisions
 - 4A Transitional provisions for hip, knee and shoulder replacements
 - 4D Revocations, transitional and saving provisions in respect of the new national registration requirements
 - 4H Revocation of Commission Decision 2002/364 on 26th May 2025 and its effect before that date
 - 4I Revocation of Commission Decision 2010/227
 - 4J Revocation of Commission Regulation (EU) No 207/2012 on 26th May 2025
 - 4K Revocation of Regulation (EU) No 722/2012 on 26th May 2025
 - 4L Revocation of Regulation (EU) No 920/2013 on 26th May 2025 and its effect before that date
 - 4M Revocation of Regulation (EU) No 2017/2185 and saving provision
 - 4N The classification criteria in Directives 2003/12 and 2005/50
 - 4O Revocation of Regulation (EU) 2017/745

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- 4P Revocation of Regulation (EU) 2017/746
- 4T References in other legislation to Directives 90/385, 93/42 and 98/79

PART II

General Medical Devices

- 5. Interpretation of Part II
- 6. Scope of Part II
- 7. Classification of general medical devices
- 7A Registration of persons placing general medical devices on the market
- 8. Essential requirements for general medical devices
- 9. Determining compliance of general medical devices with relevant essential requirements
- 10. UK marking of general medical devices
- 10A UK(NI) indication: general medical devices
- 11. UK marking of general medical devices that come within the scope of this Part and other legislation
- 12. Exemptions from regulations 8 and 10
- 13. Procedures for affixing a UK 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
- 17. Manufacturers etc. and conformity assessment procedures for general medical devices
- 18. Approved bodies and the conformity assessment procedures for general medical devices
- 19. Registration of persons placing general medical devices on the market
- 19A Additional requirements relating to use of animal tissues
- 19B Obligations in Part II of these Regulations which are met by complying with obligations in Directive 93/42
- 19C Obligations in Part II and III of these Regulations which are met by complying with obligations in Regulation (EU) 2017/745

PART III

Active Implantable Medical Devices

- 20. Interpretation of Part III
- 21. Scope of Part III
- 21A Registration of persons placing active implantable medical devices on the market
- 21B Registration of persons placing active implantable medical devices on the market
- 21C Requirement to appoint a UK responsible person for active implantable medical devices
- 22. Essential requirements for active implantable medical devices
- 23. Determining compliance of active implantable medical devices with relevant essential requirements
- 24. UK marking of active implantable medical devices
- 24A UK(NI) indication: active implantable medical devices
- 25. UK marking of active implantable medical devices that come within the scope of this Part and other legislation
- 26. Exemptions from regulations 22 and 24

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- 27. Procedures for affixing a UK 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
- 30A Obligations in Part III which are met by complying with obligations in Directive 90/385
- 31. Approved 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
- 33A Registration etc. of persons placing in vitro diagnostic medical devices on the market
- 34. Essential requirements for in vitro diagnostic medical devices
- 34A Approval requirement for coronavirus test devices
- 34B Public sector use of coronavirus test devices
- 34C Transitional provisions for coronavirus test devices
- 34D Exemption for coronavirus test devices in conformity with Regulation (EU) 2017/746 and Regulation (EU) 2022/1107
- 35. Determining compliance of in vitro diagnostic medical devices with relevant essential requirements
- 36. UK marking of in vitro diagnostic medical devices
- 36A UK(NI) indication: in vitro diagnostic medical devices
- 37. UK marking of in vitro diagnostic devices that come within the scope of this Part and other legislation
- 38. In vitro diagnostic medical devices not ready for use
- 38A Applications for approval of coronavirus test devices
- 38B Performance requirements for coronavirus test devices
- 38C Register of approved coronavirus test devices
- 39. Exemptions from this Part
- 39A Exemptions for coronavirus test devices
- 40. Procedures for affixing a UK marking to in vitro diagnostic medical devices
- 41. Manufacturers etc. and conformity assessment procedures for in vitro diagnostic medical devices
- 42. Approved bodies and the conformity assessment procedures for in vitro diagnostic medical devices
- 43. Devices for performance evaluation
- 44. Registration of persons placing in vitro diagnostic medical devices on the market or for performance evaluation
- 44ZA Obligations in Part IV which are met by complying with obligations in Directive 98/79
- 44ZB Obligations in Part IV of these Regulations which are met by complying with obligations in Regulation (EU) 2017/746

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PART V

Approved Bodies, Conformity Assessment Bodies and Marking of Products

- 44A Interpretation of Part V
- A45 Meaning of approved body and UK notified body
- 45. Designation etc. of approved bodies
- 46. Choice of approved bodies and conformity assessment bodies
- 47. General matters relating to approved bodies
- 47A Register of approved bodies
- 48. Designation etc. of ... conformity assessment bodies
- 49. Fees charged by approved bodies and conformity assessment bodies
- 50. Products incorrectly marked with an approved body or conformity assessment body number
- 51. Products incorrectly marked with a UK 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 of approved bodies
- 55. Fees payable in connection with the designation etc. of ... conformity assessment bodies
- 56. Fees payable in relation to clinical investigation notices
- 56A Fees in connection with approval of coronavirus test devices
- 56B Circumstances in which a fee is payable in relation to a consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device
- 56C Fees payable in connection with a consultation or further consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device
- 56D Fees payable in connection with pre-consultation meetings
- 57. Unpaid fees
- 58. Waivers, reductions and refunds

PART VII

General, Enforcement and Miscellaneous

- 59. Interpretation of Part VII
- 60. Status of UK responsible person
- 61. Enforcement etc.
- 62. Compliance notices
- 63. Restriction notices
- 64. Notification of decisions etc.
- 65. Centralised systems of records etc.
- 66. Revocations
- 67. Review
Signature

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SCHEDULE 1 — ASSOCIATION AGREEMENTS

1. The Agreement establishing an Association between the European Economic Community...

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 and...
4. The agreement on mutual recognition between the European Community and...
5. The agreement between the European Community and the Swiss Confederation...

SCHEDULE 2 — Mutual Recognition Agreement countries — Australia — New Zealand — Canada — The United...

SCHEDULE 2A — Modification of Annexes to Directives 90/385, 93/42, 98/79

PART 1 — Modification of Annexes to Directive 90/385

1. (1) The Annexes to Directive 90/385 are modified so that...
2. In Annex 1— (za) in Section 2, for “the functions...
3. In Annex 2— (a) for the heading substitute “Declaration of...
4. In Annex 3— (a) in the title for “EC TYPE-EXAMINATION”...
5. For Annex 4 substitute— ANNEX 4 VERIFICATION Verification is the procedure whereby the manufacturer ensures and declares...
6. For Annex 5, substitute— ANNEX 5 DECLARATION OF CONFORMITY TO...
7. In Annex 6— (a) in Section 1, for “authorised representative...
8. In Annex 7— (a) in Section 1.1 for “harmonised” substitute...
9. In Annex 8— (a) in the title for “when designating...
10. Omit Annex 9.

PART 2 — Modification of Annexes to Directive 93/42

11. (1) The Annexes to Directive 93/42 are modified so that...
12. In Annex I— (a) in Section 3, for “Article 1(2)(a)”...
13. In Annex II— (a) in the title omit “EC”;
14. In Annex III— (a) for each reference to “EC type-examination”...
15. In Annex IV— (a) omit “EC” (including in the title)...
16. In Annex V— (a) for “notified body” each time it...
17. In Annex VI— (a) omit “EC” each time it occurs...
18. In Annex VII— (a) in the title and in Section...
19. In Annex VIII— (a) in Section 1, for “authorized representative”...
20. In Annex IX for “this Directive” each time it occurs...
21. In Annex X— (a) in Section 1.1 for “harmonised standards”...
22. In Annex XI— (a) in the title, for “notified bodies”...
23. Omit Annex XII.

PART 3 — Modification of Annexes to Directive 98/79

24. (1) The Annexes to Directive 98/79 are modified so that...
25. In Annex 1— (a) in Section 3 in part A,...
26. In Annex III— (a) in the title and in Section...

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27. In Annex IV— (a) in the title, omit “EC”;
28. In Annex V— (a) in the title, omit “EC” ;...
29. In Annex VI— (a) in the title omit “EC”;
30. In Annex VII— (a) in the title and in Section...
31. In Annex VIII— (a) in Section 1—
32. In Annex IX— (a) in the title, for “notified bodies”...
33. Omit Annex X.

Explanatory Note

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