STATUTORY INSTRUMENTS

2021 No. 873

EXITING THE EUROPEAN UNION
CONSUMER PROTECTION

The Medical Devices (Amendment) (EU Exit) Regulations 2021

Sift requirements satisfied	*13th July 2021*
Made - - - -	*20th July 2021*
Laid before Parliament	*21st July 2021*
Coming into force	*11th August 2021*

THE MEDICAL DEVICES (AMENDMENT) (EU EXIT) REGULATIONS 2021

15. In regulation 32 (interpretation of Part IV), for the definition...
16. In regulation 33 (Scope of Part IV)—
17. In regulation 36 (UK marking of in vitro diagnostic medical...
18. In regulation 41 (manufacture etc. and conformity assessment procedures for...
19. In regulation 54 (fees payable in connection with the designation...
20. In regulation 59 (interpretation of Part VII) omit "or a...
21. In Schedule 2A (modification of Annexes to Directives 90/385, 93/42...

SCHEDULE 2 — Amendments to EU tertiary legislation

PART 1

Amendments to Commission Decision 2002/364/EC

1. In Article 1 (which relates to the adoption of common...
2. Omit Article 2 (which relates to the addressees of the...
3. In the Annex (which contains common technical specifications for in...

PART 2

Amendments to Commission Regulation (EU) No 207/2012

4. In Article 1 (which relates to the scope of the...
5. In Article 3 (which relates to the provision of instructions...
6. In Article 7 (which relates to access to instructions for...
7. For Article 8 (which relates to review of obligations by...
8. In Article 10 (which relates to the commencement and applicability...

PART 3

Amendments to Commission Regulation (EU) No 722/2012

9. In Article 2 (which relates to interpretation), in the stem...
10. In Article 3 (which relates to risk analysis and risk...
11. In Article 4 (which relates to verification of the fitness...
12. In Article 5 (which relates to conformity assessment procedures)—
13. Omit Articles 6 (which relates to the obligation on Member...
14. In Article 9 (which relates to entry into force and...
15. In Annex I (which relates to risk assessment, management and...
16. In Annex II (which relates to summary evaluation reports)—

PART 4

Amendments to Commission Implementing Regulation 920/2013

17. In Article 1(a) (definitions), for "Article 1(2)(c) of Directive 90/385/EEC...
18. For Article 1(c) substitute— (c) "approved body" has the same...
19. For Article 1(d) substitute— (d) "accreditation" means an attestation by...
20. Omit Article 1(e) and 1(f).
21. In Article 1(g), for "designating authority" substitute "Secretary of State"....
22. In Article 1(i), for "a designating authority's" substitute "the Secretary...
23. After Article 1insert— Article 1a In this Regulation, any reference...

24. In Article 3 (which relates to the procedure for the...
25. In Article 4(extension of renewal of designation)—
26. In Article 5 (surveillance and monitoring)— (a) in paragraph 1—...
27. For Article 6 (investigation of competence of notified bodies) substitute —...
28. Omit Articles 7 (exchange of experience on investigation and supervision...
29. For Article 9 (co-operation with accrediting bodies) substitute (without changing...
30. In Article 10 (which relates to entry into force and...
31. In Annex I (which relates to interpretation of the conformity...
32. In Annex II (the application form to be submitted when...

Explanatory Note