
STATUTORY INSTRUMENTS

2024 No. 221

**MEDICAL DEVICES
CONSUMER PROTECTION**

The Medical Devices (In Vitro Diagnostic
Devices etc.) (Amendment) Regulations 2024

Made - - - - 22nd February 2024

Coming into force 21st March 2024

THE MEDICAL DEVICES (IN VITRO DIAGNOSTIC
DEVICES ETC.) (AMENDMENT) REGULATIONS 2024

PART 1

Preliminary

1. Citation and commencement
2. Extent and application

PART 2

Amendments to primary legislation

3. Amendment to the Human Tissue Act 2004
4. Amendment to the Consumer Rights Act 2015
5. Amendment to the Medicines and Medical Devices Act 2021
6. Amendment to section 21 (compliance notices)
7. Amendment to section 42 (interpretation of Part 4)

PART 3

Amendments to secondary legislation

8. Amendment to the Medical Devices Regulations 2002
9. Amendment to regulation 2 (interpretation) in relation to Great Britain
10. Amendment to regulation 2 (interpretation) in relation to Northern Ireland
11. Amendment to regulation 2A (medical devices which are qualifying Northern Ireland goods)
12. Amendment to regulation 3ZA (revocation, transitional and saving provisions in respect of Regulation (EU) 2017/745)

Status: This is the original version (as it was originally made).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

13. Amendment to regulation 4T (references in other legislation to Directives 90/385, 93/42 and 98/79)
14. Revocation of regulation 19B (requirement to appoint a UK responsible person for general medical devices)
15. Revocation of regulation 21C (requirement to appoint a UK responsible person for active implantable medical devices)
16. Amendment to regulation 34A (approval requirement for coronavirus test devices)
17. New regulation 34D (exemption for coronavirus test devices in conformity with Regulation (EU) 2017/746 and Regulation (EU) 2022/1107)
18. Amendment to regulation 44 (registration of persons placing in vitro diagnostic medical devices on the market or for performance evaluation)
19. Revocation of regulation 44ZA (requirement to appoint a UK responsible person for placing in vitro diagnostic medical devices on the market or for performance evaluation)
20. Amendment to the Blood Safety and Quality Regulations 2005
21. Amendment to the Human Tissue (Quality and Safety for Human Application) Regulations 2007
22. Amendment to the Legislative and Regulatory Reform (Regulatory Functions) Order 2007
23. Amendment to the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012
24. Amendment to the Waste Electrical and Electronic Equipment Regulations 2013
25. Amendment to the Economic Growth (Regulatory Functions) Order 2017
26. Amendment to the Market Surveillance (Northern Ireland) Regulations 2021

PART 4

Amendments to the Medical Devices (Northern Ireland Protocol) Regulations 2021

27. Amendment to the Medical Devices (Northern Ireland Protocol) Regulations 2021
28. Amendment to regulation 2 (extent and application)
29. Amendment to regulation 3 (interpretation)
30. Amendment to regulation 4 (scope)
31. Amendment to regulation 8 (certificates of free sale – fee)
32. Amendment to regulation 10 (UK(NI) indication)
33. New Part 2A (Making available on the market and putting into service under Regulation (EU) 2017/746)
34. New regulation A11 (legal representatives and contact persons for clinical investigations)
35. Amendment to regulation 13 (arbitration following the refusal of a clinical investigation application)
36. New Part 3A (Performance studies under Regulation (EU) 2017/746)
37. Amendment to Part 4
38. Amendment to regulation 18 (notified bodies)
39. Amendment to regulation 19 (fees payable in connection with the designation of notified bodies)
40. Amendment to regulation 20 (language requirements)
41. Amendment to regulation 23 (offence of breaching certain provisions)
42. Amendment to regulation 26 (enforcement)

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

43. Amendment to Schedule 2 (fees in connection with the designation of notified bodies)
44. Amendment to Schedule 3 (provisions breach of which is an offence under regulation 23)
Signature
Explanatory Note