
DRAFT STATUTORY INSTRUMENTS

2021 No.

**MEDICAL DEVICES
CONSUMER PROTECTION**

The Medical Devices (Northern
Ireland Protocol) Regulations 2021

Made - - - - - ***

Coming into force ***

THE MEDICAL DEVICES (NORTHERN
IRELAND PROTOCOL) REGULATIONS 2021

PART 1

Preliminary

1. Citation and commencement
2. Extent and application
3. Interpretation
4. Scope

PART 2

Making available on the market and putting into service under Regulation (EU) 2017/745

5. Reprocessing of single-use devices
6. Requirement on health institutions to provide information relating to implanted devices
7. Registration of custom-made devices
8. Certificates of free sale - fee
9. Retention of documentation relating to conformity assessments and custom-made devices
10. UK(NI) indication

PART 3

Clinical investigations under Regulation (EU) 2017/745

11. Ethical review of clinical investigations
12. Prior authorisation of clinical investigations by the Secretary of State

13. Arbitration following the refusal of a clinical investigation application
14. Damage compensation in relation to clinical investigations
15. Retention of documentation relating to clinical investigations
16. Clinical investigation fees
17. Clinical investigations not carried out for a purpose specified in Article 62(1)

PART 4

Notified bodies designated under Regulation (EU) 2017/745

18. Notified bodies
19. Fees payable in connection with the designation of notified bodies

PART 5

General provision about language requirements and fees

20. Language requirements
21. Unpaid fees
22. Waivers, reductions and refunds

PART 6

Enforcement

23. Offence of breaching certain provisions
24. Defence of due diligence
25. Offences by bodies corporate
26. Enforcement

PART 7

Amendment of primary legislation

27. Investigatory powers under the Consumer Rights Act 2015
28. Amendment of the Medicines and Medical Devices Act 2021

PART 8

Amendment of the Medical Devices Regulations 2002

29. Amendments to the Medical Devices Regulations 2002
30. Amendment of regulation 2 (interpretation)
31. Amendment of regulation 2A (medical devices which are qualifying Northern Ireland goods)
32. Revocation and transitional provision
33. Amendment of regulation 10A (UK(NI) indication: general medical devices)
34. Amendment of regulation 19 (registration of persons placing general medical devices on the market)
35. Amendment of regulation 21B (registration of persons placing active implantable medical devices on the market)
36. Amendment of regulation 24A (UK(NI) indication: active implantable medical devices)
37. Amendment of regulation 36A (UK(NI) indication: in vitro diagnostic medical devices)

PART 9

Amendments of other secondary legislation

38. Amendment of the Blood Safety and Quality Regulations 2005
 39. Amendment of the Human Tissue (Quality and Safety for Human Application) Regulations 2007
 40. Amendment of the Legislative and Regulatory Reform (Regulatory Functions) Order 2007
 41. Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016
 42. Amendment of the Economic Growth (Regulatory Functions) Order 2017
 43. Amendment of the Market Surveillance (Northern Ireland) Regulations 2021
- Signature

SCHEDULE 1 — Fees for clinical investigations

SCHEDULE 2 — Fees in connection with the designation of notified bodies

SCHEDULE 3 — Provisions breach of which is an offence under regulation 23

Explanatory Note