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DRAFT STATUTORY INSTRUMENTS

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**2023 No.**

**MEDICAL DEVICES  
HEALTH AND SAFETY  
FEES AND CHARGES**

The Medical Devices and Blood Safety and  
Quality (Fees Amendment) Regulations 2023

*Made* - - - -

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*Coming into force*

*1st April 2023*

**THE MEDICAL DEVICES AND BLOOD SAFETY AND  
QUALITY (FEES AMENDMENT) REGULATIONS 2023**

PART 1

Preliminary and Revocation

1. Citation, commencement, extent and application
2. Revocation

PART 2

Amendment of the Medical Devices Regulations 2002

3. Amendment of the Medical Devices Regulations 2002
4. Amendment of regulation 2 in relation to England, Scotland and Wales (interpretation)
5. Amendment of regulation 16 in relation to England, Scotland and Wales (procedures for general medical devices for clinical investigations)
6. Amendment of regulation 29 in relation to England, Scotland and Wales (procedures for active implantable medical devices for clinical investigations)
7. Amendment of regulation 52 (interpretation of Part VI)
8. Amendment of regulation 53 in relation to England, Scotland and Wales (fees in connection with the registration of devices and changes to registration details)

9. Amendment of regulation 53 in relation to Northern Ireland (fees in connection with the registration of devices and changes to registration details)
10. Amendment of regulation 54 in relation to England, Scotland and Wales (fees payable in connection with the designation of approved bodies)
11. Amendment of regulation 55 in relation to England, Scotland and Wales (fees payable in connection with the designation etc. of conformity assessment bodies)
12. Amendment of regulation 55 in relation to Northern Ireland (fees payable in connection with the designation etc. of conformity assessment bodies)
13. Amendment of regulation 56 in relation to England, Scotland and Wales (fees payable in relation to clinical investigation notices)
14. New regulation 56B
15. New regulation 56C
16. New regulation 56D

### Part 3

#### Amendment of the Blood Safety and Quality Regulations 2005

17. Amendment of the Blood Safety and Quality Regulations 2005

### Part 4

#### Amendment of the Medical Devices (Northern Ireland Protocol) Regulations 2021

18. Amendment of the Medical Devices (Northern Ireland Protocol) Regulations 2021
  19. Amendment of regulation 7 (registration of custom-made devices)
  20. Amendment of regulation 16 (clinical investigation fees)
  21. New regulation 17A (advice in relation to intended clinical investigations)
  22. Amendment of regulation 19 (fees payable in connection with the designation of notified bodies)
  23. New Part 4A
  24. Amendment of Schedule 1 (fees for clinical investigations)
  25. Amendment of Schedule 2 (fees in connection with the designation of notified bodies)
- Signature  
Explanatory Note