STATUTORY INSTRUMENTS

# 2021 No. 905

# MEDICAL DEVICES CONSUMER PROTECTION

The Medical Devices (Northern Ireland Protocol) Regulations 2021

Made - - -Coming into force 26th July 2021 27th July 2021

# THE MEDICAL DEVICES (NORTHERN IRELAND PROTOCOL) REGULATIONS 2021

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# Preliminary

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- 3. Interpretation
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- 5. Reprocessing of single-use devices
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- 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
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- 18. Notified bodies
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Fees for consultation in relation to the safety, quality and usefulness of a medicinal substance incorporated in a device

- 19A Interpretation of Part 4A
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- 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)
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- 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
- 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

**Changes to legislation:** There are currently no known outstanding effects for the The Medical Devices (Northern Ireland Protocol) Regulations 2021.