STATUTORY INSTRUMENTS

# 2012 No. 1501

# **HUMAN TISSUE**

The Quality and Safety of Organs Intended for Transplantation Regulations 2012

Made - - -

11th June 2012

Laid before Parliament 14th June 2012 Coming into force in accordance with regulation 1(2) and (3)

# THE QUALITY AND SAFETY OF ORGANS INTENDED FOR TRANSPLANTATION REGULATIONS 2012

PART 1

Citation, commencement and extent

1. Citation and commencement

2. Extent

# PART 2

Interpretation and designation of the competent authority

- 3. Interpretation
- 4. Designation of the competent authority

# PART 3

### Licensing

- 5. Licensing requirement
- 6. Application of the 2004 Act in relation to licences under Schedule 1
- 7. Extension of other provisions of the 2004 Act to Scotland
- 8. Breach of requirement to hold a licence
- 9. Preconditions to grant of a licence
- 10. Duty of the licence holder
- 11. Directions
- 12. Guidance

## PART 4

#### Other obligations of the Authority

- 13. Framework and compliance with licensing conditions and directions
- 14. Records and reports
- 15. Living donors
- 16. Serious adverse events and serious adverse reactions
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- 18. Organs sent to or received from another country
- 19. European Union network of competent authorities
- 20. Requirement for the Authority to provide information

## PART 5

#### General

- 21. Arrangements by the Authority for assistance with functions
- 22. Offences by bodies corporate
- 23. Licences: transitional arrangements
- 24. Review

### PART 5A

Power to amend data sets specified in Schedule 1A in relation to Great Britain

- 24A Power for appropriate authority to amend Schedule 1A in relation to Great Britain
- 24B Scope and nature of powers
- 24C Scrutiny of regulations

### PART 6

### Amendments to other legislation

- 25. Amendment of the 2004 Act
- 26. Amendment of the 2006 Regulations
- 27. Amendment of the Human Tissue Act 2006 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2004
- 28. Amendment of the 2007 Regulations
- 29. Amendment of the 2006 Scotland Regulations Signature

SCHEDULE 1 — Licences for the purposes of regulation 5

- 1. The Authority may on application grant a licence for the...
- 2. Licensing conditions
- 3. It shall be a condition of a licence for a...
- 4. It shall be a condition of a licence for the...
- 5. It shall be a condition of a licence for the...
- 6. It shall be a condition of a licence for the...
- 7. Where any of the information specified in part A of...
- 8. It shall be a condition of a licence for a...
- 9. The conditions in paragraph 8(b) do not apply where transportation...

10. Fees

SCHEDULE 1A — Organ and Donor Characterisation PART A — Minimum data set

- 1. The information to be collected pursuant to paragraph 5(b)(i) of... PART B — Complementary data set
- 2. The information to be collected pursuant to paragraph 5(b)(ii) of...

SCHEDULE 2 — Directions of the Authority

- 1. For the purposes of ensuring consistent compliance with the licensing...
- 2. For the purpose of ensuring consistent standards in relation to...
- 3. For the purpose of ensuring compliance with the requirements of...

Explanatory Note

**Changes to legislation:** There are currently no known outstanding effects for the The Quality and Safety of Organs Intended for Transplantation Regulations 2012.