
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

1. Citation and commencement
2. Extent

PART 2

3. Interpretation
4. Designation of the competent authority

PART 3

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

the Authority

13. Framework and compliance with licensing conditions and directions

Status: This is the original version (as it was originally made).

14. Records and reports
15. Living donors
16. Serious adverse events and serious adverse reactions
17. Traceability
18. Organs sent to another country
19. European Union network of competent authorities
20. Requirement for the Authority to provide information

PART 5

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

PART 6

25. Amendment of the 2004 Act
26. Amendment of the 2006 Regulations
27. Amendment of the Human Tissue Act 2004 (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 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...

Explanatory Note