Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin (Text with EEA relevance) (repealed)

Article 1	
Article 2	
Article 3	
Article 4	
Article 5	
Article 6	
Article 7	
Article 8	
Article 9	
Article 10	

## ANNEX

## 1. RISK ANALYSIS AND RISK MANAGEMENT

- 1.1. Justification for the use of animal tissues or derivatives
- 1.2. Assessment procedure
  - 1.2.1. Animals as a source of material
  - 1.2.2. Geographical sourcing
  - 1.2.3. Nature of starting tissue
  - 1.2.3.1. Sheep and goats
    - 1.2.3.2. Cattle
  - 1.2.4. Inactivation or removal of transmissible agents
  - 1.2.5. Quantities of animal starting tissues or derivatives required to produce...
  - 1.2.6. Tissues or derivatives of animal origin coming into contact with...
  - 1.2.7. Route of administration
- 1.3. Review of the assessment
- 2. EVALUATION OF CLASS III MEDICAL DEVICES BY NOTIFIED BODIES