

Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (Text with EEA relevance)

- Article 1 (1) This Regulation lays down particular requirements in relation to...
- Article 2 For the purposes of this Regulation, the following definitions apply...
- Article 3 (1) Before lodging an application for a conformity assessment for...
- Article 4 (1) The Secretary of State must verify on a regular...
- Article 5 (1) Conformity assessment procedures for medical devices referred to in...
- Article 6 Without prejudice to Article 7(2), Member States shall take all...
- Article 7 (1) Holders of EC design-examination certificates or EC type-examination certificates...
- Article 8 Directive 2003/32/EC is repealed with effect from 29 August 2013....
- Article 9 This Regulation enters into force on the twentieth day following...
- Signature

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ANNEX I

1. RISK ANALYSIS AND RISK MANAGEMENT
  - 1.1. Justification for the use of animal tissues or derivatives
  - 1.2. Process of risk assessment
    - 1.2.1. Animals as a source of material
    - 1.2.2. Geographical sourcing
    - 1.2.3. Nature of starting tissue
    - 1.2.4. Slaughtering and processing controls to prevent cross contamination
    - 1.2.5. Inactivation or removal of TSE infectious agents
      - 1.2.5.1. For devices which cannot withstand an inactivation or elimination process...
      - 1.2.5.2. For other devices, if claims are made by the manufacturer...
    - 1.2.6. Quantities of animal tissues or derivatives required to produce one...
    - 1.2.7. Tissues or derivatives of animal origin coming into contact with...
    - 1.2.8. Route of administration
  - 1.3. Review of the risk assessment
2. EVALUATION BY APPROVED BODIES
  - 2.1. Information of the Approved Body regarding changes and new information...
  - 2.2. Renewal of certificates
  - 2.3. Increase of the overall TSE risk

**Changes to legislation:** Commission Regulation (EU) No 722/2012 is up to date with all changes known to be in force on or before 10 April 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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### 3. RIGOROUS PROCESSES FOR TALLOW DERIVATIVES AS REFERRED TO IN ARTICLE...

#### ANNEX II

##### Details relating to the submitting approved body

##### Details relating to the submitting notified body

1. Name of approved body
2. Approved body number
3. Country
4. Sent by
5. Contact person
6. Telephone
7. Fax
8. E-mail
9. Client reference (name of manufacturer and, if applicable, of authorised...
10. Confirmation that the submitting approved body has been designated by...

##### Data relating to the (active implantable) medical device

11. # Active implantable medical device # Other medical device
11. Product description and composition
12. Information on intended use
13. Starting material
  13. EDQM certificate available # YES # NO (If the EDQM...
  13. Information regarding the nature of the starting tissue(s): animal species(s):...
14. A description of the key elements adopted to minimise the...
15. An estimate of the TSE risk arising from the use...
16. A justification for the use of animal tissues or derivatives...
17. The approach to the auditing of source establishments and suppliers...

##### Approved Body Statement

18. Conclusion of this assessment:

##### Date of submission

19. This report was sent on ... to the Coordinating Competent...

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- (1) [OJ L 189, 20.7.1990, p. 17.](#)
- (2) [OJ L 169, 12.7.1993, p. 1.](#)
- (3) [OJ L 105, 24.4.2003, p. 18.](#)
- (4) [OJ L 300, 14.11.2009, p. 1.](#)
- (5) Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3) ([OJ C 73, 5.3.2011, p. 1.](#)).
- (6) <http://www.efsa.europa.eu/en/topics/topic/bse.htm>
- (7) [http://ec.europa.eu/food/fs/bse/scientific\\_advice08\\_en.print.html](http://ec.europa.eu/food/fs/bse/scientific_advice08_en.print.html)
- (8) See [http://ec.europa.eu/health/scientific\\_committees/emerging/opinions/scmpmd/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/emerging/opinions/scmpmd/index_en.htm)

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**Changes and effects yet to be applied to :**

- Regulation applied by S.I. 2002/618, reg. 4K(2)(4) (as inserted) by [S.I. 2019/791 reg. 3\(7\)](#) (This amendment not applied to legislation.gov.uk. The affecting text in reg. 3(7) is omitted (31.12.2020 immediately before IP completion day) by virtue of S.I. 2020/1478, reg. 1(3), Sch. 2 para. 9(h))
- Regulation applied by S.I. 2002/618, reg. 4K(3) (as inserted) by [S.I. 2019/791 reg. 3\(7\)](#) (This amendment not applied to legislation.gov.uk. The affecting text in reg. 3(7) is omitted (31.12.2020 immediately before IP completion day) by virtue of S.I. 2020/1478, reg. 1(3), Sch. 2 para. 9(h))
- Regulation revoked by S.I. 2002/618, reg. 4K (as substituted) by [S.I. 2021/873 Sch. 1 para. 4](#)