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)

ANNEX I

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...

(**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

(**8**) See http://ec.europa.eu/health/scientific_committees/emerging/opinions/scmpmd/index_en.htm

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.
View outstanding changes

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