ANNEX II

[F1Details relating to the submitting approved body]

Textual Amendments

F1 Annex 2 heading substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 16(a)(i)**

Details relating to the submitting notified body

1. Name of [F2approved body]

Textual Amendments

F2 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 16(a)(ii)**

2. [F3Approved body] number

Textual Amendments

F3 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 16(a)(iii)**

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 representative)

10. [F4Confirmation that the submitting approved body has been designated by the Secretary of State for the conformity assessment of]

active implantable medical devices manufactured utilising tissues of animal origin subject to Regulation (EU) No 722/2012,

medical devices manufactured utilising tissues of animal origin subject to Regulation (EU) No 722/2012

Textual Amendments

F4 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 16(a)(iv)**

Data relating to the (active implantable) medical device

11.

(a) # Active implantable medical device # Other medical device

11.

(b) Product description and composition

12. Information on intended use

13. Starting material

13.

(a) EDQM certificate available # YES # NO

(If the EDQM certificate is available, it must be submitted with this summary evaluation report.)

13.

(b) Information regarding
- the nature of the starting tissue(s):
- animal species(s):
- geographical source(s):

14. A description of the key elements adopted to minimise the risk of infection:

15. An estimate of the TSE risk arising from the use of the product, taking into account the likelihood of contamination of the product, the nature and duration of patient exposure:

16. A justification for the use of animal tissues or derivatives in the medical device, including a rationale for the acceptability of the overall TSE risk estimate, the evaluation of alternative materials and the expected clinical benefit:

17. The approach to the auditing of source establishments and suppliers for the animal material used by the device manufacturer:

[F5Approved Body Statement]

18. Conclusion of this assessment:

Based on the evaluation of data and the assessment process it is our preliminary decision that the application meets the requirements of conformity with

[F6 Part 3 of the Medical Devices Regulations 2002**]** # **[F7**Part 2 of the Medical Devices Regulations 2002**]**

Textual Amendments

F6 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 16(b)(ii)**

F7 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 16(b)(iii)**

and Regulation (EU) No 722/2012.

Date of submission

19. This report was sent on … to the Coordinating Competent Authority of … to inform the Competent Authorities of the other Member States and the Commission and to seek their comments, if any.

Changes to legislation:
Commission Regulation (EU) No 722/2012, ANNEX II is up to date with all changes known to be in force on or before 09 August 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