ANNEX II

Summary Evaluation Report in accordance with Article 5(4) of Regulation (EU) No 722/2012

Details relating to the submitting notified body

1. Name of notified body

2. Notified 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 representative)

10. Confirmation that, in accordance with Article 11 of Directive 90/385/EEC and Article 16 of Directive 93/42/EEC, respectively, and Article 4 of Regulation (EU) No 722/2012, the submitting notified body has been designated by its competent authority 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

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:

Notified 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

Council Directive 90/385/EEC # Council Directive 93/42/EEC

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.

Status:
Point in time view as at 31/01/2020.

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 15 July 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.