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 the placing on the market and/or putting into service of medical devices, including active implantable medical devices, manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

2 This Regulation shall apply to animal tissues, as well as their derivatives, originating from bovine, ovine and caprine species, deer, elk, mink and cats.

3 Collagen, gelatine and tallow used for the manufacturing of medical devices shall meet at least the requirements as fit for human consumption laid down in Regulation (EC) No 1069/2009.

4 This Regulation shall not apply to any of the following:

a Tallow derivatives, processed under conditions at least as vigorous as those laid down in Section 3 of Annex I;

b medical devices referred to in paragraph 1, which are not intended to come into contact with the human body or which are intended to come into contact with intact skin only.

Article 2

For the purposes of this Regulation, the following definitions apply in addition to the definitions set out in **[**[F1]the Medical Devices Regulations 2002**]**:

(a) ‘cell’ means the smallest organised unit of any living form which is capable of independent existence and of replacement of its own substance in a suitable environment;

(b) ‘tissue’ means an organisation of cells, extra-cellular constituents or both;

(c) ‘derivative’ means a material obtained from animal tissue through one or more treatments, transformations or steps of processing;

(d) ‘non-viable’ means having no potential for metabolism or multiplication;

(e) ‘TSEs’ means all transmissible spongiform encephalopathies as defined in Article 3(1)(a) of Regulation (EC) No 999/2001 of the European Parliament and of the Council[(1)];

(f) ‘TSE infectious agents’ means unclassified pathogenic agents which are capable of transmitting TSEs;

(g) ‘reduction, elimination or removal’ means a process by which the number of TSE infectious agents is reduced, eliminated or removed in order to prevent infection or pathogenic reaction;

(h) ‘inactivation’ means a process by which the ability to cause infection or pathogenic reaction by TSE infectious agents is reduced;

(i) ‘source country’ means the country or countries in which the animal was born, has been reared and/or has been slaughtered;

(j) 'starting materials' means raw materials or any other product of animal origin out of which, or with the help of which, the devices referred to in Article 1(1) are produced.

Textual Amendments

F1 Words in Art. 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 9**

Article 3

[F2 1 Before lodging an application for a conformity assessment for the purpose of complying with regulation 13 or regulation 27 of the Medical Devices Regulations 2002, the manufacturer of medical devices referred to in Article 1(1) of this Regulation or their UK responsible person must carry out the risk analysis and risk management scheme set out in Annex I to this Regulation.**]**

2 For custom-made devices and devices intended for clinical investigation which fall under Article 1(1), the statement of the manufacturer or his authorised representative and the documentation in accordance with Annex 6 to Directive 90/385/EEC or Annex VIII to Directive 93/42/EEC, respectively, shall also address compliance with the particular requirements set out in section 1 of Annex I to this Regulation.

Textual Amendments

F2 Art. 3(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 10**

Article 4

[F3 1 The Secretary of State must verify on a regular basis that approved bodies designated under Part 5 of the Medical Devices Regulations 2002 have up-to-date knowledge and expertise of the medical devices referred to in Article 1(1), in order to assess the conformity of those devices with the provisions of those Regulations and with the particular requirements of Annex I to this Regulation.**]**

F4 2 . . . . . .

Textual Amendments

F3 Art. 4(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 11(a)**

F4 Art. 4(2) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 11(b)**

Article 5

1 Conformity assessment procedures for medical devices referred to in Article 1(1) shall include the evaluation of compliance of the devices with the essential requirements of **[**F5 Part 3 or Part 2 of the Medical Devices Regulations 2002**]**, respectively, and the particular requirements laid down in Annex I to this Regulation.

2 **[**F6Approved bodies**]** shall assess the documentation submitted by the manufacturer to verify that the benefits of the device outweigh the residual risks. Particular account shall be taken of:

a the manufacturer's risk analysis and risk management process;

b the justification for the use of animal tissues or derivatives, taking into consideration lower risk tissues or synthetic alternatives;

c the results of elimination and inactivation studies or results of the analysis of relevant literature;

d the manufacturer's control of the sources of raw materials, finished products, production process, testing, and subcontractors;

e the need to audit matters related to the sourcing and processing of animal tissues and derivatives, processes to eliminate or inactivate pathogens, including those activities carried out by suppliers.

3 **[**F7Approved bodies**]** shall, during the evaluation of the risk analysis and risk management in the framework of the conformity assessment procedure, take account of the TSE certificate of suitability issued by the European Directorate for the Quality of Medicines, hereinafter 'TSE certificate of suitability', for starting materials, where available.

Where additional information is necessary to assess the suitability of the starting material for a given medical device, **[**F8approved bodies**]** may require submission of additional information to allow the evaluation as set out in paragraphs 1 and 2.

[F9 4 Before issuing a design-examination certificate or a type-examination certificate the approved body must inform the Secretary of State of their assessment carried out pursuant to paragraph 2 by means of a summary evaluation report in accordance with Annex II to this Regulation.

5 The Secretary of State may submit comments on the summary evaluation report referred to in paragraph 4 within the following deadlines:

a in relation to medical devices using starting materials for which a TSE certificate of suitability as referred to in paragraph 3 has been submitted, within four weeks from the date on which the approved body informed the Secretary of State pursuant to paragraph 4;

b in relation to medical devices using starting materials for which a TSE certificate of suitability has not been submitted, within 12 weeks from the date on which the approved body informed the Secretary of State pursuant to paragraph 4.

6 The approved bodies must—

a give due consideration to any comments received in accordance with paragraph 5;

b provide an explanation as regards this consideration, including any due justification not to take account of one or more of the comments received, along with their final decisions to the Secretary of State.**]**

7 The manufacturer shall collect, evaluate and submit to the **[**F10approved body**]** information regarding changes with regard to the animal tissue or derivatives used for the device or with regard to the TSE risk in relation to the device. Where such information leads to an increase of the overall TSE risk, the provisions of **[**F11paragraphs 1 to 3**]** are applicable.

Textual Amendments

F5 Words in Art. 5(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 12(a)**

F6 Words in Art. 5(2) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 12(b)**

F7 Words in Art. 5(3) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 12(c)(i)**

F8 Words in Art. 5(3) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 12(c)(ii)**

F9 Art. 5(4)-(6) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 12(d)**

F10 Words in Art. 5(7) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 12(e)(i)**

F11 Words in Art. 5(7) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 12(e)(ii)**

F12 Article 6

. . . . . .

Textual Amendments

F12 Art. 6 omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 13**

F13 Article 7

. . . . . .

Textual Amendments

F13 Art. 7 omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 13**

Article 8

F14

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Textual Amendments

F14 Art. 8 omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 13**

Article 9

This Regulation enters into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 29 August 2013 except for Article 4 which shall apply from the date of entry into force of this Regulation.

F15

...

Done at Brussels, 8 August 2012.

For the Commission

The President

José Manuel BARROSO

Textual Amendments

F15 Words in Signature omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 14**

(**1**) OJ L 147, 31.5.2001, p. 1.

Changes to legislation:
Commission Regulation (EU) No 722/2012 is up to date with all changes known to be in force on or before 20 May 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