Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin (Text with EEA relevance) (repealed)

Article 1

1 This Directive lays down detailed specifications in relation to risks of transmitting transmissible spongiform encephalophathies (TSE) under normal conditions of use to patients or others, via medical devices manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

2 The animal tissues covered by this Directive are those originating from bovine, ovine and caprine species, as well as deer, elk, mink and cats.

3 Collagen, gelatin and tallow used for the manufacturing of medical devices, shall meet at least the requirements as fit for human consumption.

4 This Directive does not apply to 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 Directive, the following definitions shall apply in addition to the definitions set out in Directive 93/42/EEC:

(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 and/or extra-cellular constituents;

(c) ‘derivative’ means a material obtained from an animal tissue by a manufacturing process such as collagen, gelatine, monoclonal antibodies;

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

(e) ‘transmissible agents’ means unclassified pathogenic entities, prions and such entities as bovine spongiform encephalophathies agents and scrapie agents;

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

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

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

(i) ‘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.

Article 3

Before lodging an application for a conformity assessment pursuant to Article 11(1) of Directive 93/42/EEC, the manufacturer of medical devices referred to in Article 1(1), shall carry out the risk analysis and the risk management scheme set out in the Annex to this Directive.

Article 4

Member States shall verify that bodies notified under Article 16 of Directive 93/42/EEC have up-to-date knowledge of the medical devices referred to in Article 1(1), in order to assess the conformity of those devices referred to in Article 1(1) with the provisions of Directive 93/42/EEC and with the specifications laid down in the Annex to this Directive.

If, on the basis of that verification, it is necessary for a Member State to amend the tasks of a notified body, that Member State shall notify the Commission and the other Member States accordingly.

Article 5

1 Conformity assessment procedures for medical devices referred to in Article 1(1), shall include the evaluation of their compliance with the essential requirements of Directive 93/42/EEC and the specifications laid down in the Annex to this Directive.

2 Notified bodies shall evaluate the manufacturer's risk analysis and risk management strategy, and in particular:

a the information provided by the manufacturer;

b the justification for the use of animal tissues or derivatives;

c the results of elimination and/or inactivation studies or of literature search;

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

e the need to audit matters related to sourcing, including third party supplies.

3 Notified 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', for starting materials, where available.

4 Except for medical devices using starting materials for which a TSE certificate has been issued as referred to in paragraph 3, national bodies shall, through their competent authority, seek the opinion of the competent authorities of the other Member States on their evaluation of and conclusions on the risk analysis and risk management of **[**[X1]the tissues or the derivatives intended to be utilised in the medical device**]** as established by the manufacturer.

Before issuing an EC design-examination certificate or an EC type-examination certificate, the notified bodies shall give due consideration to any comments received within 12 weeks from the date on which the opinion of the national competent authorities was sought.

Editorial Information

X1 Substituted by Corrigendum to Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with

respect to medical devices utilising tissues of animal origin (Official Journal of the European Union L 105 of 26 April 2003).

Article 6

Member States shall take all necessary steps to ensure that medical devices referred to in Article 1(1) are placed on the market and put into service only if they comply with the provisions of Directive 93/42/EEC and the specifications laid down in the Annex to this Directive.

Article 7

1 Holders of EC design-examination certificates or EC type-examination certificates issued before 1 April 2004 for medical devices referred to in Article 1(1) shall apply for a complementary EC design-examination certificate or EC type-examination certificate attesting to compliance with the specifications laid down in the Annex to this Directive.

2 Until 30 September 2004, Member States shall accept the placing on the market and the putting into service of medical devices referred to in Article 1(1) which are covered by an EC design-examination certificate or an EC type-examination certificate issued before 1 April 2004.

Article 8

1 Member States shall adopt and publish before 1 January 2004 the provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions with effect from 1 April 2004.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference at the time of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 9

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 10

This Directive is addressed to the Member States.