SLOVENSKI STANDARD
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Medicinski pripomočki, ki uporabljajo živalska tkiva in njihove derivate - 2. del: Nadzor pri nabavi, zbiranju in ravnanju z njimi ISO/DIS 22442-2:2018)

Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO/DIS 22442-2:2018)

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 2: Kontrollen der Beschaffung, Materialgewinnung und Handhabung (ISO/DIS 22442-2:2018)

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés - Partie 2: Contrôles de l'origine, de la collecte et du traitement (ISO/DIS 22442-2:2018)

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Medical devices utilizing animal tissues and their derivatives —

Part 2: Controls on sourcing, collection and handling

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés —

Partie 2: Contrôles de l'origine, de la collecte et du traitement

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www. iso. org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www. iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 194, *Biological and clinical evaluation of medical devices*, Subcommittee SC 1, *Tissue product safety*.

This third edition cancels and replaces the second edition (ISO 22442-2:2015), of which it constitutes a minor revision.

The major changes are:

— Update of weblink on stunning technique in Annex A, A.3.2.5 Note 1;

— Clarification on scope inclusion of cervid-sourced materials, and other TSE susceptible species;

— Clarification on atypical BSE types, especially in combination with intracranial applications;

— Enhanced expectation of using validated biochemical testing to establish TSE presence;

— Update of weblink in Annex C;

— Update of bibliography;

— Editorial revision.

A list of all parts in the ISO 22442- series can be found on the ISO website.

Introduction

Certain medical devices utilize materials of animal origin.

Animal tissues and their derivatives are used in the design and manufacture of medical devices to provide performance characteristics that have been chosen for advantages over non-animal based materials. The range and quantities of materials of animal origin in medical devices vary. These materials can comprise a major part of the device (e.g. bovine/porcine heart valves, bone substitutes for use in dental or orthopaedic applications, haemostatic devices), can be a product coating or impregnation (e.g. collagen, gelatine, heparin), or can be used in the device manufacturing process (e.g. tallow derivatives such as oleates and stearates, foetal calf serum, enzymes, culture media).

Tissues and derivatives for use in medical devices are typically obtained by the manufacturer from a range of sources such as animal herds or flocks and commercial harvesting (including fishing). Some specialized industries also process materials of animal origin to manufacture a finished product (e.g. gelatine) which is incorporated as a raw material into the finished medical device by the manufacturer.

To show compliance with this document, its specified requirements should be fulfilled. The guidance given in the notes and informative annexes is not normative and is not provided as a checklist for auditors.

Medical devices utilizing animal tissues and their derivatives —

Part 2: Controls on sourcing, collection and handling

1 Scope

This document specifies requirements for controls on the sourcing, collection, and handling (which includes storage and transport) of animals and tissues for the manufacture of medical devices utilizing materials of animal origin other than *in vitro* diagnostic medical devices. It applies where required by the risk management process as described in ISO/DIS 22442-1.

NOTE 1 Selective sourcing is considered to be especially important for transmissible spongiform encephalopathy (TSE) risk management, i.e. when utilising animal tissue and/or their derivative originating from bovine, ovine and caprine species, deer, elk, mink or cats.

In addition, local safety regulation may be applied to ensure a clean basic handling of animals towards viral and bacterial loads (see also 5.5). The manufacturers should refer to ISO 22442-3 for information on the validation of the elimination and/or inactivation of viruses and TSE agents.

This document does not cover the utilization of human tissues in medical devices.

This document does not specify a quality management system for the control of all stages of production of medical devices.

It is not a requirement of this document to have a full quality management system during manufacture, but it does specify requirements for some of the elements of a quality management system. Attention is drawn to the standards for quality management systems (see ISO 13485) that control all stages of production or reprocessing of medical devices. The quality management system elements that are required by this document can form a part of a quality management system conforming to ISO 13485.

NOTE 2 A general principle for the application of this International Standard is that it is advisable to give due consideration to the requirements and recommendations contained in all three parts of the standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/DIS 22442-1:2018, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/DIS 22442-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
collection
removal of tissues from animals

3.2
closed herd or colony
herd or colony governed by standard operating procedures (SOPs) that specify criteria restricting admission of new animals to assure that all introduced animals are at the same or higher health standard, compared to the residents of the herd or colony. Such SOPs should include:

a) a documented veterinary monitoring process;

b) logging of TSE history;

c) a process to prevent feeding of mammalian-derived protein;

d) a fully documented breeding history;

e) a fully documented use of veterinary medicines and vaccines;

f) a process of traceability towards each individual animal;

g) a process to control introduction of genetic material from herds with the deviating TSE status

3.3
veterinarian
person designated by the relevant competent authority as suitably qualified for the responsibility delegated to him or her relating to ante- and post-mortem inspection of animals and/or relevant certification

Note 1 to entry: Under certain jurisdictions, it is a requirement that the veterinarian be a professionally qualified person in veterinary medicine.

Note 2 to entry: Under certain jurisdictions, the function of inspection and of certification can be carried out by different individuals. In such cases, the certificate can be signed by a person who is not designated by the competent authority. This function is covered in the quality management system of the medical device manufacturer.

4 General requirements

4.1 General

Apply the requirements of this document as determined by the risk assessment (see ISO/DIS 22442-1).

Annex A shall be applied as appropriate.

4.2 Quality system elements

A documented system shall be established and maintained to control the quality of materials of animal origin and shall be verified by the medical device manufacturer. Specific requirements relating to collection are included in Clause 6.

This system shall address the animal source and the following factors:

a) specification of the geographical origin (such as country or region) of the animal material, state of health of the animals, and acceptance criteria for animals taking into account the source-species, perceived risk from pathogens, and ability to obtain appropriate assurances;

NOTE 1 The geographical origin can include the animal's place of birth and the countries or regions in which it has lived during its lifetime as well as its place of slaughter. It is advisable that the manufacturer document the extent to which the geographical origin of the animal can be traced taking into account the application of risk management (see ISO/DIS 22442-1).

b) hygiene and quality assurance requirements to be met by the slaughterer including the provisions in the slaughterhouse to prevent cross-contamination within and between animals;

c) procedures for the collection, preservation, handling, storage, and transport of materials of animal origin;

d) documented evidence of the effectiveness of controls defined in a), b), and c);

e) records to be maintained [including as a minimum items a), b), c), and d). See also 5.5].

For the control of processed animal material suppliers, the medical device manufacturer shall document, to the extent feasible, the practices of the specialized industries to which clauses of the various parts of ISO 22442 have been applied.

Manufacturers should apply relevant provisions of ISO 22442 to natural substances such as milk, hair, and wool, although these are not covered by the definition of derivatives.

NOTE 2 The use of risk analysis/risk management tools [such as HACCP, FMEA (see ISO 14971:2007, Annex G)] are useful in determining residual risk.

4.3 Procedures

The documented procedures and instructions required by this part of ISO 22442 shall be established, implemented, and maintained. These procedures and instructions shall be approved on issue and shall be controlled as follows.

The manufacturer shall establish and maintain procedures to control all documents and data that relate to the requirements of this document. These documents shall be reviewed and approved for adequacy by authorized personnel prior to issue.

This control shall ensure that:

a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed, and

b) obsolete documents are promptly removed from all points of issue or use.

Changes to documents shall be reviewed and approved by the same functions/organizations that performed the original review and approval unless specifically designated otherwise. The designated organizations shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the nature of each change shall be identified in the document or the appropriate attachments.

A master list or equivalent document control procedure shall be established to identify the current revision of documents in order to preclude the use of non-applicable documents.

4.4 Personnel

Responsibility for the collection, handling, and storage of materials shall be assigned to qualified personnel as follows.

The manufacturer shall establish and maintain procedures for identifying the training needs and provide for the training of all personnel performing activities affecting quality.