SLOVENSKI STANDARD
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Medicinski pripomočki, ki uporabljajo živalska tkiva in njihove derivate - 1. del: Uporaba obvladovanja tveganja (ISO/DIS 22442-1:2018)

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

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 1: Anwendung des Risikomanagements (ISO/DIS 22442-1:2018)

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés - Partie 1: Application de la gestion des risques (ISO/DIS 22442-1:2018)

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Medical devices utilizing animal tissues and their derivatives —

Part 1: Application of risk management

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés —

Partie 1: Application de la gestion des risques

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Contents

Page

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 voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee 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 (EN ISO 22442-1:2015), which has undergone minor revision.

The major changes are:

— Update of weblinks in C.2 Collagen, bullet point 1, C.3.3 Bones s the starting material and C.4.4 Stunning methods;

— Update of weblink in D.3.3 Geographical sourcing;

— 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).

ISO 14971 is a general standard which specifies a process for a manufacturer by identifying hazards and hazardous situations associated with medical devices, including *in vitro* medical devices, to estimate and evaluate the risks associated with those hazards, to control these risks and to monitor the effectiveness of the control throughout the life cycle. This document provides additional requirements and guidance for the evaluation of medical devices manufactured utilizing animal tissues or derivatives which are non-viable or rendered non-viable.

This document is intended to cover medical devices including active implantable medical devices such as implantable infusion pumps.

This document does not apply to *in vitro* diagnostic devices.

This document can only be used in combination with ISO 14971 and is not a “stand-alone” Standard.

NOTE 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 1: Application of risk management

1 Scope

This document applies to medical devices other than *in vitro* diagnostic medical devices manufactured utilizing materials of animal origin, which are non-viable or have been rendered non-viable. It specifies, in conjunction with ISO 14971, a procedure to identify the hazards and hazardous situations associated with such devices, to estimate and evaluate the resulting risks, to control these risks, and to monitor the effectiveness of that control. Furthermore, it outlines the decision process for the residual risk acceptability, taking into account the balance of residual risk, as defined in ISO 14971, and expected medical benefit as compared to available alternatives. This document is intended to provide requirements and guidance on risk management related to the hazards typical of medical devices manufactured utilizing animal tissues or derivatives such as:

a) contamination by bacteria, moulds or yeasts;

b) contamination by viruses;

c) contamination by agents causing Transmissible Spongiform Encephalopathies (TSE);

d) material responsible for undesired pyrogenic, immunological or toxicological reactions.

For parasites and other unclassified pathogenic entities, similar principles can apply.

This document does not stipulate levels of acceptability which, because they are determined by a multiplicity of factors, cannot be set down in such an International Standard except for some particular derivatives mentioned in Annex C. Annex C stipulates levels of TSE risk acceptability for tallow derivatives, animal charcoal, milk and milk derivatives, wool derivatives and amino acids.

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

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

NOTE 1 It is not a requirement of this document to have a full quality management system during manufacture. However, attention is drawn to International Standards for quality management systems (see ISO 13485) that control all stages of production or reprocessing of medical devices.

NOTE 2 For guidance on the application of this document see Annex A.

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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 22442-2:2015, *Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling*

ISO 22442-3:2007, *Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971 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
animal
any vertebrate or invertebrate [including amphibian, arthropod (e.g. crustacean), bird, coral, fish, reptile, mollusc and mammal] excluding humans (*Homo sapiens*)

3.2
cell
smallest organized unit of any living form which is capable of independent existence and of replacement of its own substance in a suitable environment

3.3
derivative
substance obtained from an animal material by a manufacturing process which is directly involved in the production of the medical device or which is a final part of the medical device

EXAMPLE Hyaluronic acid, collagen, gelatine, monoclonal antibodies, chitosan, albumin.

3.4
elimination
removal
process by which the number of transmissible agents is reduced

Note 1 to entry: The effectiveness of the process for the elimination of viruses and TSE agents should be expressed mathematically in terms of a reduction factor (see C.2 and ISO 22442-3:2007, Annex F).

Note 2 to entry: Elimination aims to prevent infection or pathogenic reaction caused by transmissible agents.

3.5
inactivation
process by which the ability to cause infection or pathogenic reaction by a transmissible agent is reduced

Note 1 to entry: The effectiveness of the process for inactivation of viruses and TSE agents should be expressed mathematically in terms of a reduction factor (see ISO 22442-3:2007, Annex F).

Note 2 to entry: Inactivation aims to prevent infection by, and replication of, transmissible agents.

3.6
medical device
any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s):

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;

— investigation, replacement, modification, or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body;

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

Note 1 to entry: This definition has been developed by the Global Harmonization Task Force (GHTF).[40]

Note 2 to entry: This document does not apply to *in vitro* diagnostic devices.

3.7
non-viable
having no potential for metabolism or multiplication

3.8
technical agreement
binding contract between two or more parties that assigns responsibilities for technical requirements

3.9
tissue
organization of cells and/or extra-cellular constituents

3.10
transmissible agents
bacteria, mould, yeast, parasites, viruses, TSE agents and unclassified pathogenic entities

4 Risk management process

4.1 General

The manufacturer shall justify the use of animal material (including the choice of animal species and tissues) based on the residual risk acceptability, taking into account the balance of residual risk and expected medical benefit, as compared to available alternatives.

The requirements of ISO 14971 apply. Compliance with these requirements shall be verified by inspection of the risk management file.

NOTE Further discussion of medical benefits and the risk/benefit analysis can be found in ISO 14971.

4.2 Risk analysis

4.2.1 Identification of qualitative and quantitative characteristics related to the safety of medical devices

4.2.1.1 Does the device come into contact with the patient or other persons?

The quantity of material, the contact surface area and the type(s) of the material coming into contact with body tissues or fluids as well as the type of body tissue or fluid it comes into contact with, shall be addressed in the risk analysis. For TSE, guidance can be found in D.3.7.

NOTE 1 Medical devices such as orthopaedic shoes or components such as leather straps that come into contact only with intact skin represent a low infective risk.