SLOVENSKI STANDARD

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Živalska tkiva in njihovi derivati, uporabljeni v proizvodnji medicinskih pripomočkov – 2. del: Nadzor pri nabavi, zbiranju in ravnanju

Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 2: Controls on sourcing, collection and handling

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 2: Kontrollen der Gewinnung, Sammlung und Handhabung

Tissus animaux et leurs dérivés utilisés dans la fabrication des dispositifs médicaux - Partie 2: Contrôles de l'origine, de la collecte et du traitement

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EUROPEAN STANDARD

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English version

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Tissus animaux et leurs dérivés utilisés dans la fabrication des dispositifs médicaux - Partie 2: Contrôles de l'origine, de la collecte et du traitement

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This European Standard was approved by CEN on 20 April 2000.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 316 "Medical devices utilizing tissues", the secretariat of which is held by IBN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

This Part of EN 12442 has been considered by CEN/TC 316 as one of a series of European Standards concerned with the development of European Standards for medical devices manufactured utilizing tissues or derivatives of animal origin, non-viable or rendered non-viable. These standards are:

EN 12442-1	Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 1: Analysis and management of risk.
EN 12442-3	Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Medical devices may contain materials of animal origin.

The use of animal tissues and derivatives will give performance characteristics expected to be superior to non-animal based materials such as metal, plastics or textiles. The range and quantities of materials of animal origin in medical devices vary. These materials may comprise a major part of the device (e.g. bovine/porcine heart valves, catgut sutures, haemostatic devices), a product coating or impregnation (e.g. heparin, gelatin, collagen), or aid the manufacturing stages of production (e.g. tallow).

Tissues 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. gelatin) which is incorporated as a raw material into the finished medical device by the manufacturer.

> NOTE: To show compliance with this standard, its specified requirements should be fulfilled. The guidance given in the Notes and in informative Annexes is not obligatory and is not provided as a checklist for auditors.

1 Scope

1.1 This Part of EN 12442 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.

NOTE 1: Requirements for the risk analysis of the use of materials of animal origin in medical devices are described in EN 12442-1.

NOTE 2: Conventional processes used for sterilization, when used for the treatment of animal tissues for medical devices, have not been shown to be completely effective in inactivating the causative agents of spongiform encephalopathies. Selective sourcing is thus extremely important. Manufacturers should refer to EN 12442-3 for information on the validation of the elimination and/or inactivation of viruses and transmissible agents.

1.2 This Part of EN 12442 does not cover the utilization of human tissues in medical devices.

1.3 This Part of EN 12442 does not describe a quality assurance system for the control of all stages of manufacture.

NOTE: Attention is drawn to the standards for quality systems (see EN ISO 9001 and EN 46001 or EN ISO 9002 and EN 46002) which relate to all stages of manufacture. It is not a requirement of this standard to have a complete quality system during manufacture but certain elements of such a system are required.

1.4 This Part of EN 12442 does not consider the effect of any method of elimination and/or inactivation on the suitability of the medical device for its intended use.

2 Normative References

This European standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies (including amendments).

EN 12442-1:2000 Animal tissues and their derivatives utilized in the manufacture of medical devices – Part 1: Analysis and management of risk.

EN 12442-3:2000 Animal tissues and their derivatives utilized in the manufacture of medical devices – Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents.

3 Terms and definitions

For the purposes of this Part of EN 12442 the following terms and definitions apply:

3.1
animal
all vertebrates including fish, amphibians, reptiles, birds and mammals excluding humans (*Homo sapiens*) [EN 12442-1 and EN 12442-3].

3.2
collection
removal of tissues from animals.

3.3
derivative
material obtained from an animal tissue by a manufacturing process [EN 12442-1].

NOTE 1: Examples of derivatives are hyaluronic acid, collagen, gelatin, monoclonal antibodies.

NOTE 2: Natural substances such as milk, hair, and wool are excluded by this definition.

3.4
inactivation
process by which the ability to cause infection or pathogenic reaction by a virus and/or transmissible agent is reduced [EN 12442-1 and EN 12442-3].

NOTE 1: The effectiveness of the process should be expressed mathematically in terms of a reduction factor. (See Annex D of EN 12442-3:2000).

NOTE 2: Inactivation aims to prevent infection and replication of viruses or transmissible agents.

3.5
low risk herd ("closed herd"; "well-monitored herd")
herd in which for at least the previous six years:

a) there has been documented veterinary monitoring;
b) there has been no case of BSE;
c) there has been no feeding of mammalian-derived protein;
d) there is a fully documented breeding history;
e) each animal is traceable, and
f) genetic material has been introduced only from herds with the same BSE-free status.

NOTE: Attention is drawn to possible future regulatory definition of this term.

3.6
medical device
any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

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

NOTE: This definition is identical with that given in Council Directive 93/42/EEC.

3.7
tissue
organization of cells and/or extra-cellular constituents [EN 12442-1 and EN 12442-3].

3.8
veterinarian
"official veterinarian" designated by the relevant government competent authority in the country concerned or person suitably qualified for the responsibility that has been delegated by the relevant government competent authority.

4 General requirements

4.1 Quality system elements

A documented system shall be established and maintained to control the quality of materials of animal origin. This system shall include at least the following:

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: The geographical origin may include the animal's place of birth and the countries or regions in which it has lived during its lifetime, and its place of slaughter as well. The manufacturer should document the extent to which the geographical origin of the animal can be traced taking into account the risk analysis and management (see EN 12442-1).

b) hygiene and quality assurance requirements to be met by the slaughterer;

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

d) records to be maintained (including as a minimum items a), b) and c) above; see also 6.2);

e) audit of the effectiveness of controls defined in a), b) and c) above.

4.2 Procedures

The documented procedures and instructions required by this standard 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 Part of EN 12442. 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;

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.

4.3 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. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience as required. Appropriate records of training shall be maintained.

Personnel directly involved in the collection and handling of material of animal origin shall be personnel employed by the device manufacturer or designated and adequately trained abattoir employees or the equivalent. The same requirements apply to personnel of all subcontractors. The manufacturer shall identify the in-house verification requirements, and shall provide adequate resources and assign trained personnel for verification activities. Audits shall be carried out by personnel independent of those having direct responsibility for the work being performed.

4.4 Current requirements and guidance

Due account shall be taken of relevant current EU or international requirements or guidance , including the OIE International Animal Health Code (see Bibliography).

5 Sourcing; general; species and strain

NOTE: Clauses 5, 6, 7, 8 and 9 should be applied by suppliers of animal materials, intermediaries and medical device manufacturers as relevant.

5.1 The risk of certain diseases is dependent on the source species and possibly strain and this shall be taken into account.

5.2 The procedures adopted before, during and after slaughter shall not prejudice the risk reduction provided by sourcing in particular by avoiding cross-contamination.

6 Sourcing of animal materials: Inspection, certification and traceability

6.1 Sourcing of animal material shall, if technically practicable, be subject to control and individual inspection by a veterinarian. There will however be some source species where this