

SVENSK STANDARD

SS-EN ISO 22442-2:2020

Medicintekniska produkter som innehåller vävnader från djur
och derivat därav –

Del 2: Kontroller av ursprung, utvinning och hantering
(ISO 22442-2:2020)

Medical devices utilizing animal tissues and their derivatives –
Part 2: Controls on sourcing, collection and handling
(ISO 22442-2:2020)



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Europastandarden EN ISO 22442-2:2020 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 22442-2:2020.

Denna standard ersätter SS-EN ISO 22442-2:2015, utgåva 2

The European Standard EN ISO 22442-2:2020 has the status of a Swedish Standard. This document contains the official version of EN ISO 22442-2:2020.

This standard supersedes the SS-EN ISO 22442-2:2015, edition 2

LÄSANVISNINGAR FÖR STANDARDER

I dessa anvisningar behandlas huvudprinciperna för hur regler och yttre begränsningar anges i standardiseringsprodukter.

Krav

Ett krav är ett uttryck i ett dokumentets innehåll som anger objektivet verifierbara kriterier som ska uppfyllas och från vilka ingen avvikelse tillåts om efterlevnad av dokumentet ska kunna åberopas. Krav uttrycks med hjälpverbet ska (eller ska inte för förbud).

Rekommendation

En rekommendation är ett uttryck i ett dokumentets innehåll som anger en valmöjlighet eller ett tillvägagångssätt som bedöms vara särskilt lämpligt utan att nödvändigtvis nämna eller utesluta andra. Rekommendationer uttrycks med hjälpverbet bör (eller bör inte för avrådanden).

Instruktion

Instruktioner anges i imperativ form och används för att ange hur något görs eller utförs. De kan underordnas en annan regel, såsom ett krav eller en rekommendation. De kan även användas självständigt, och är då att betrakta som krav.

Förklaring

En förklaring är ett uttryck i ett dokumentets innehåll som förmedlar information. En förklaring kan uttrycka tillåtelse, möjlighet eller förmåga. Tillåtelse uttrycks med hjälpverbet får (eller motsatsen behöver inte). Möjlighet och förmåga uttrycks med hjälpverbet kan (eller motsatsen kan inte).

READING INSTRUCTIONS FOR STANDARDS

These instructions cover the main principles for the use of provisions and external constraints in standardization deliverables.

Requirement

A requirement is an expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled, and from which no deviation is permitted if conformance with the document is to be claimed. Requirements are expressed by the auxiliary shall (or shall not for prohibition).

Recommendation

A recommendation is an expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable, without necessarily mentioning or excluding others. Recommendations are expressed by the auxiliary should (or should not for dissuasion).

Instruction

An instruction is expressed in the imperative mood and is used in order to convey an action to be performed. It can be subordinated to another provision, such as a requirement or a recommendation. It can also be used independently and is then to be regarded as a requirement.

Statement

A statement is an expression, in the content of a document, that conveys information. A statement can express permission, possibility or capability. Permission is expressed by the auxiliary may (its opposite being need not). Possibility and capability are expressed by the auxiliary can (its opposite being cannot).

EUROPEAN STANDARD

EN ISO 22442-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2020

ICS 11.100.20

Supersedes EN ISO 22442-2:2015

English Version

Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2020)

Dispositifs médicaux utilisant des tissus animaux et leurs dérivés - Partie 2: Contrôles de l'origine, de la collecte et du traitement (ISO 22442-2:2020)

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 2: Kontrollen der Beschaffung, Materialgewinnung und Handhabung (ISO 22442-2:2020)

This European Standard was approved by CEN on 2 December 2020.

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 CEN-CENELEC 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 CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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 of 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 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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 206, *Biological and clinical evaluation of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 22442-2:2015).

The main changes compared to the previous version are as follows:

- update of the weblink on stunning technique in [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.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

European foreword

This document (EN ISO 22442-2:2020) has been prepared by Technical Committee ISO/TC 194 "Biological and clinical evaluation of medical devices" in collaboration with Technical Committee CEN/TC 206 "Biological and clinical evaluation of medical devices" the secretariat of which is held by DIN.

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 June 2021, and conflicting national standards shall be withdrawn at the latest by June 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 22442-2:2015.

This document 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 the relationship with EU Directive(s) see informative [Annex ZA](#), which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard "within the meaning of [Annex ZA](#)", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between normative references and dated EN and ISO standards

| Normative references as listed in Clause 2 of the ISO standard | Equivalent dated standard | |
|--|---------------------------|------------------|
| | EN | ISO or IEC |
| ISO 22442-1 | EN ISO 22442-1:2020 | ISO 22442-1:2020 |

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 22442-2:2020 has been approved by CEN as EN ISO 22442-2:2020 without any modification.

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.

This document is intended to be used in conjunction with the other two parts of the ISO 22442 series. Local safety regulations can apply. The manufacturers should refer to ISO 22442-3 for information on the validation of the elimination and/or inactivation of viruses and TSE agents.

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.

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 22442-1.

NOTE Selective sourcing is 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.

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.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 22442-1, *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 22442-1 and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 collection

removal of tissues from animals

3.2 closed herd

herd governed by standard operating procedures (SOPs) that specify criteria restricting admission of new animals to ensure that all introduced animals are at the same or higher health standard, compared to the residents of the herd

Note 1 to entry: Such SOPs typically include:

Note 2 to entry: a) a documented veterinary monitoring process;